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Rule R313-25. License Requirements for Land Disposal of Radioactive Waste - General Provisions.

As in effect on September 1, 2002

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R313-25-1. Purpose and Scope.

The rules in this chapter establish procedures, criteria, and terms and conditions upon which the Department issues licenses for the land disposal of wastes received from other persons. The requirements of R313-25 are in addition to, and not in substitution for, other applicable requirements of these rules.

R313-25-2. Definitions.

As used in R313-25, the following definitions apply:

"Active maintenance" means significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in R313-25-19 and R313-25-20 are met. Active maintenance may include the pumping and treatment of water from a disposal unit, the replacement of a disposal unit cover, or other episodic or continuous measures. Active maintenance does not include custodial activities like repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Commencement of construction" means clearing of land, excavation, or other substantial action that could adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the disposal site.

"Disposal" means the isolation of wastes from the biosphere by placing them in a land disposal facility.

"Disposal site" means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit may be a trench.

"Engineered barrier" means a man-made structure or device intended to improve the land disposal facility's performance under R313-25.

"Hydrogeologic unit" means a soil or rock unit or zone that has a distinct influence on the storage or movement of ground water.

"Inadvertent intruder" means a person who may enter the disposal site after closure and engage in

activities unrelated to post closure management, such as agriculture, dwelling construction, or other pursuits which could, by disturbing the site, expose individuals to radiation.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in R313-25, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive waste.

"Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care, and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Stability" means structural stability.

"Surveillance" means monitoring and observation of the disposal site to detect needs for maintenance or custodial care, to observe evidence of intrusion, and to ascertain compliance with other license and regulatory requirements.

"Treatment" means the stabilization or the reduction in volume of waste by a chemical or a physical process.

"Waste" means those low-level radioactive wastes as defined in Section 19-3-102 that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as it does in the Low-Level Radioactive Waste Policy Act, Pub.L. 96-573, 94 Stat. 3347; thus, the term denotes radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, waste does not mean byproduct material as defined in 42 U.S.C. 2011(e)(2) of the Atomic Energy Act, uranium or thorium tailings and waste.

R313-25-3. Siting Criteria and Pre-licensing Plan Approval for Commercial Radioactive Waste Disposal Facilities.

(1) Persons proposing to construct or operate commercial radioactive waste disposal facilities, including waste incinerators, shall obtain a plan approval from the Executive Secretary before applying for a license. Plans shall meet the siting criteria and plan approval requirements of Section R313-25-3 and Section 19-3-105.

(2) The siting criteria and plan approval requirements in R313-25-3 apply to prelicensing plan approval applications.

(3) Treatment and disposal facilities, including commercial radioactive waste incinerators, shall not be located:

(a) within or underlain by:

(i) national, state, and county parks, monuments, and recreation areas; designated wilderness and wilderness study areas; wild and scenic river areas;

(ii) ecologically and scientifically significant natural areas, including wildlife management areas and

habitats for listed or proposed endangered species as designated by federal law;

(iii) 100 year floodplains;

(iv) areas 200 feet from Holocene faults;

(v) underground mines, salt domes and salt beds;

(vi) dam failure flood areas;

(vii) areas subject to landslide, mud flow, or other earth movement, unless adverse impacts can be mitigated;

(viii) farmlands classified or evaluated as "prime", "unique", or of "statewide importance" by the U.S. Department of Agricultural Soil Conservation Service under the Prime Farmland Protection Act;

(ix) areas five miles of existing permanent dwellings, residential areas, and other habitable structures, including schools, churches, and historic structures;

(x) areas five miles of surface waters including intermittent streams, perennial streams, rivers, lakes, reservoirs, and wetlands;

(xi) areas 100 feet of uranium mill tailings;

(xii) areas 1000 feet of archeological sites to which adverse impacts cannot reasonably be mitigated;

(xiii) recharge zones of aquifers containing ground water which has a total dissolved solids content of less than 10,000 mg/l; or

(xiv) drinking water source protection areas designated by the State Drinking Water Committee;

(b) in areas:

(i) above or underlain by aquifers containing ground water which has a total dissolved solids content of less than 500 mg/l and which aquifers do not exceed state ground water standards for pollutants;

(ii) above or underlain by aquifers containing ground water which has a total dissolved solids content between 3000 and 10,000 mg/l when the distance from the surface to the ground water is less than 100 ft.;

(iii) areas, such as areas of extensive withdrawal of water, gas, or oil;

(iv) above or underlain by weak and unstable soils, including soils that lose their ability to support foundations as a result of hydrocompaction, expansion, or shrinkage;

(v) above or underlain by karst terrains.

(4) Incinerators associated with land disposal facilities may not be located above aquifers containing ground water which has a total dissolved solids content below 3000 mg/l. Incinerators not associated with ground disposal facilities shall not be located above aquifers containing ground water which has a total dissolved solids content below 500 mg/l.

(5) Facilities may not be located within a distance to existing drinking water wells and watersheds for public water supplies of one year ground water travel time plus 1000 feet for incinerators and of five years ground water travel time plus 1000 feet for land disposal facilities.

(6) The plan approval application shall include hydraulic conductivity and other information necessary

to estimate adequately the ground water travel distance.

(7) The plan approval application shall include the results of studies adequate to identify the presence of ground water aquifers in the area of the proposed site and to assess the quality of the ground water of all aquifers identified in the area of the proposed site.

(8) The Executive Secretary may require the applicant to conduct vadose zone or other near surface monitoring.

(9) Emergency response and safety.

(a) The plan approval application shall demonstrate the availability and adequacy of emergency services, including medical and fire response. The application shall provide evidence that the applicant has coordinated emergency response plans with local and regional emergency response resources.

(b) The plan approval application shall include plans for responding to emergencies both at the site and those involving the transport of wastes within the state. Details of the proposed emergency response plan shall be given in the plan approval application and will be stipulated in the plan approval and radioactive materials license.

(c) The plan approval application shall show proposed routes for transportation of radioactive wastes within the state. The Executive Secretary will not approve plans that propose radioactive waste transportation routes over roads or bridges where weight restrictions would be exceeded. The Executive Secretary will not approve plans that pose adverse impact or risk of harm to inhabited areas. The plan approval application shall address risks to inhabited areas, including both residential and non-residential areas; the width, condition, and types of roads to be used; roadside development on proposed routes; seasonal and climatic factors which may affect safety; alternate emergency access to the facility; the type, size, and configuration of vehicles proposed to haul wastes; transportation restrictions on proposed routes; and the transportation means and routes available to evacuate the population at risk in the event of accidents, including spills and fires.

(10) Siting Authority. The Executive Secretary recognizes that Titles 10 and 17 of the Utah Code give cities and counties authority for local use planning and zoning. Nothing in R313-25-3 precludes cities and counties from establishing additional requirements as provided by applicable state and federal law.

R313-25-4. License Required.

(1) Persons shall not receive, possess, or dispose of waste at a land disposal facility unless authorized by a license issued by the Executive Secretary pursuant to R313-25 and R313-22.

(2) Persons shall file an application with the Executive Secretary pursuant to R313-22-32 and obtain a license as provided in R313-25 before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license and other penalties established by law and rules.

R313-25-5. Content of Application.

In addition to the requirements set forth in R313-22-33, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in R313-25-6 through R313-25-10.

R313-25-6. General Information.

The general information shall include the following:

(1) identity of the applicant including:

(a) the full name, address, telephone number, and description of the business or occupation of the applicant;

(b) if the applicant is a partnership, the names and addresses of the partners and the principal location where the partnership does business;

(c) if the applicant is a corporation or an unincorporated association;

(i) the state where it is incorporated or organized and the principal location where it does business; and

(ii) the names and addresses of its directors and principal officers; and

(d) if the applicant is acting as an agent or representative of another person in filing the application, the applicant shall provide, with respect to the other person, information required under R313-25-6(1).

(2) Qualifications of the applicant shall include the following;

(a) the organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

(b) the technical qualifications, including training and experience of the applicant and members of the applicant's staff, to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in R313-25-6(2)(a) shall be provided;

(c) a description of the applicant's personnel training program; and

(d) the plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.

(3) A description of:

(a) the location of the proposed disposal site;

(b) the general character of the proposed activities;

(c) the types and quantities of waste to be received, possessed, and disposed of;

(d) plans for use of the land disposal facility for purposes other than disposal of wastes; and

(e) the proposed facilities and equipment; and

(4) proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.

R313-25-7. Specific Technical Information.

The application shall include certain technical information. The following information is needed to determine whether or not the applicant can meet the performance objectives and the applicable technical requirements of R313-25:

(1) A description of the natural and demographic disposal site characteristics shall be based on and determined by disposal site selection and characterization activities. The description shall include

geologic, geochemical, geotechnical, hydrologic, ecologic, archaeologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

(2) Descriptions of the design features of the land disposal facility and of the disposal units for near-surface disposal shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

(3) Descriptions of the principal design criteria and their relationship to the performance objectives.

(4) Descriptions of the natural events or phenomena on which the design is based and their relationship to the principal design criteria.

(5) Descriptions of codes and standards which the applicant has applied to the design, and will apply to construction of the land disposal facilities.

(6) Descriptions of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and ground water access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances which might affect meeting the performance objectives of R313-25

(7) A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closures and to eliminate the need for active maintenance after closure.

(8) Identification of the known natural resources at the disposal site whose exploitation could result in inadvertent intrusion into the wastes after removal of active institutional control.

(9) Descriptions of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility.

(10) Descriptions of quality assurance programs, tailored to low-level waste disposal, including audit and managerial controls, for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste.

(11) A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in R313-25-19 and monitoring of occupational radiation exposure to ensure compliance with the requirements of R313-15 and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. The applicant shall describe procedures, instrumentation, facilities, and equipment appropriate to both routine and emergency operations.

(12) A description of the environmental monitoring program to provide data and to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.

(13) Descriptions of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

(14) A description of the facility electronic recordkeeping system as required in R313-25-33.

R313-25-8. Technical Analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of R313-25 will be met:

(1) Analyses demonstrating that the general population will be protected from releases of radioactivity shall consider the pathways of air, soil, ground water, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate a reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in R313-25-19.

(2) Analyses of the protection of inadvertent intruders shall demonstrate a reasonable assurance that the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

(3) Analysis of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analysis shall provide reasonable assurance that exposures will be controlled to meet the requirements of R313-15.

(4) Analyses of the long-term stability of the disposal site shall be based upon analyses of active natural processes including erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

R313-25-9. Institutional Information.

The institutional information submitted by the applicant shall include:

(1) A certification by the federal or state agency which owns the disposal site that the agency is prepared to accept transfer of the license when the provisions of R313-25-16 are met and will assume responsibility for institutional control after site closure and for post-closure observation and maintenance.

(2) Evidence, if the proposed disposal site is on land not owned by the federal or a state government, that arrangements have been made for assumption of ownership in fee by the federal or a state agency.

R313-25-10. Financial Information.

This information shall demonstrate that the applicant is financially qualified to carry out the activities for which the license is sought. The information shall meet other financial assurance requirements of R313- 25.

R313-25-11. Requirements for Issuance of a License.

A license for the receipt, possession, and disposal of waste containing radioactive material will be issued by the Executive Secretary upon finding that:

(1) the issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

(2) the applicant is qualified by reason of training and experience to carry out the described disposal operations in a manner that protects health and minimizes danger to life or property;

(3) the applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control, are adequate to protect the public health and safety as specified in the performance objectives of R313-25-19;

(4) the applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in accordance with the performance objectives of R313-25-20;

(5) the applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in accordance with R313-15;

(6) the applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and post-closure institutional control plans are adequate to protect the public health and safety in that they will provide reasonable assurance of the long-term stability of the disposed waste and the disposal site and will eliminate to the extent practicable the need for continued maintenance of the disposal site following closure;

(7) the applicant's demonstration provides reasonable assurance that the requirements of R313-25 will be met;

(8) the applicant's proposal for institutional control provides reasonable assurance that control will be provided for the length of time found necessary to ensure the findings in R313-25-11(3) through (6) and that the institutional control meets the requirements of R313-25-28.

(9) the financial or surety arrangements meet the requirements of R313-25.

R313-25-12. Conditions of Licenses.

(1) A license issued under R313-25, or a right thereunder, may not be transferred, assigned, or disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to a person, unless the Executive Secretary finds, after securing full information, that the transfer is in accordance with the provisions of the Radiation Control Act and Rules and gives his consent in writing in the form of a license amendment.

(2) The Executive Secretary may require the licensee to submit written statements under oath.

(3) The license will be terminated only on the full implementation of the final closure plan, including post-closure observation and maintenance, as approved by the Executive Secretary.

(4) The licensee shall submit to the provisions of the Act now or hereafter in effect, and to all findings and orders of the Executive Secretary. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, and orders issued in accordance with the terms of the Act and these rules.

(5) Persons licensed by the Executive Secretary pursuant to R313-25 shall confine possession and use of the materials to the locations and purposes authorized in the license.

(6) The licensee shall not dispose of waste until the Executive Secretary has inspected the land disposal facility and has found it to conform with the description, design, and construction described in the application for a license.

(7) The Executive Secretary may incorporate, by rule or order, into licenses at the time of issuance or thereafter, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as the Executive Secretary deems appropriate or necessary in order to:

(a) protect health or to minimize danger to life or property;

(b) require reports and the keeping of records, and to provide for inspections of licensed activities as the Executive Secretary deems necessary or appropriate to effectuate the purposes of the Radiation Control Act and Rules.

(8) The authority to dispose of wastes expires on the expiration date stated in the license. An expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

R313-25-13. Application for Renewal or Closure.

(1) An application for renewal or an application for closure under R313-25-14 shall be filed at least 90 days prior to license expiration.

(2) Applications for renewal of a license shall be filed in accordance with R313-25-5 through 25-10. Applications for closure shall be filed in accordance with R313-25-14. Information contained in previous applications, statements, or reports filed with the Executive Secretary under the license may be incorporated by reference if the references are clear and specific.

(3) If a licensee has filed an application in proper form for renewal of a license, the license shall not expire unless and until the Executive Secretary has taken final action to deny application for renewal.

(4) In evaluating an application for license renewal, the Executive Secretary will apply the criteria set forth in R313-25-11.

R313-25-14. Contents of Application for Site Closure and Stabilization.

(1) Prior to final closure of the disposal site, or as otherwise directed by the Executive Secretary, the licensee shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included in the original license application submitted and approved under R313-25-7(7). The plan shall include the following:

(a) additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period;

(b) the results of tests, experiments, or other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or other tests, experiments, or analyses pertinent to the long-term containment of emplaced waste within the disposal site;

(c) proposed revision of plans for:

(i) decontamination or dismantlement of surface facilities;

(ii) backfilling of excavated areas; or

(iii) stabilization of the disposal site for post-closure care.

(d) Significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

(2) Upon review and consideration of an application to amend the license for closure submitted in accordance with R313-25-14(1), the Executive Secretary shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of R313-25 will be met.

R313-25-15. Post-Closure Observation and Maintenance.

The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the Executive Secretary in accordance with R313- 25-16. The licensee shall remain responsible for the disposal site for an additional five years. The Executive Secretary may approve closure plans that provide for shorter or longer time periods of post-closure observation and maintenance, if sufficient rationale is developed for the variance.

R313-25-16. Transfer of License.

Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the Executive Secretary finds:

(1) that the disposal site was closed according to the licensee's approved disposal site closure plan;

(2) that the licensee has provided reasonable assurance that the performance objectives of R313-25 have been met;

(3) that funds for care and records required by R313-25-33(4) and (5) have been transferred to the disposal site owner;

(4) that the post-closure monitoring program is operational and can be implemented by the disposal site owner; and

(5) that the Federal or State agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under R313-25-11(8) will be met.

R313-25-17. Termination of License.

(1) Following the period of institutional control needed to meet the requirements of R313-25-11, the licensee may apply for an amendment to terminate the license.

(2) This application will be reviewed in accordance with the provisions of R313-22-32.

(3) A license shall be terminated only when the Executive Secretary finds:

(a) that the institutional control requirements of R313-25-11(8) have been met;

(b) that additional requirements resulting from new information developed during the institutional control period have been met;

(c) that permanent monuments or markers warning against intrusion have been installed; and

(d) that records required by R313-25-33(4) and (5) have been sent to the party responsible for institutional control of the disposal site and a copy has been sent to the Executive Secretary immediately prior to license termination.

R313-25-18. General Requirement.

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals do not exceed the limits stated in R313-25-19 and 25-22.

R313-25-19. Protection of the General Population from Releases of Radioactivity.

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals shall not result in an annual dose exceeding an equivalent of 0.25 mSv (0.025 rem) to the whole body, 0.75 mSv (0.075 rem) to the thyroid, and 0.25 mSv (0.025 rem) to any other organ of any member of the public. No greater than 0.04 mSv (0.004 rem)committed effective dose equivalent or total effective dose equivalent to any member of the public shall come from groundwater. Reasonable efforts should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

R313-25-20. Protection of Individuals from Inadvertent Intrusion.

Design, operation, and closure of the land disposal facility shall ensure protection of any individuals inadvertently intruding into the disposal site and occupying the site or contacting the waste after active institutional controls over the disposal site are removed.

R313-25-21. Protection of Individuals During Operations.

Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in R313-15 of these rules, except for release of radioactivity in effluents from the land disposal facility, which shall be governed by R313-25-19. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable, ALARA.

R313-25-22. Stability of the Disposal Site After Closure.

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required.

R313-25-23. Disposal Site Suitability Requirements for Land Disposal - Near-Surface Disposal.

(1) The primary emphasis in disposal site suitability is given to isolation of wastes and to disposal site features that ensure that the long-term performance objectives are met.

(2) The disposal site shall be capable of being characterized, modeled, analyzed and monitored.

(3) Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of R313-25.

(4) Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of R313-25.

(5) The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, "Floodplain Management Guidelines."

(6) Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

(7) The disposal site shall provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Executive Secretary will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being

met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

(8) The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.

(9) Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, vulcanism, or similar phenomena may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of R313-25 or may preclude defensible modeling and prediction of long-term impacts.

(10) Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with sufficient such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of R313-25, or may preclude defensible modeling and prediction of long-term impacts.

(11) The disposal site shall not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of R313-25 or significantly mask the environmental monitoring program.

R313-25-24. Disposal Site Design for Near-Surface Land Disposal.

(1) Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

(2) The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives will be met.

(3) The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.

(4) Covers shall be designed to minimize, to the extent practicable, water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

(5) Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

(6) The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

R313-25-25. Near Surface Land Disposal Facility Operation and Disposal Site Closure.

(1) Wastes designated as Class A pursuant to R313-15-307 of these rules shall be segregated from other wastes by placing them in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of R313-25. This segregation is not necessary for Class A wastes if they meet the stability requirements of R313-15-308(2).

(2) Wastes designated as Class C pursuant to R313-15-307 shall be disposed of so that the top of the waste is a minimum of five meters below the top surface of the cover or shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

(3) Except as provided in R313-25-1(1), only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. Wastes shall be disposed of in accordance with the requirements of R313-25-25(4) through 11.

(4) Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

(5) Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

(6) Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of R313-15-105 at the time the license is transferred pursuant to R313-25-16.

(7) The boundaries and locations of disposal units shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the boundaries of the units can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey or National Geodetic Survey control stations, shall be established on the site to facilitate surveys. The United States Geological Survey or National Geodetic Survey control stations shall provide horizontal and vertical controls as checked against United States Geological Survey or National Geodetic Survey record files.

(8) A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in R313-25-26(4) and take mitigative measures if needed.

(9) Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as the disposal units are filled and covered.

(10) Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

(11) Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.

(12) Proposals for disposal of waste that are not generally acceptable for near-surface disposal because the wastes form and disposal methods shall be different and, in general, more stringent than those specified for Class C waste, may be submitted to the Executive Secretary for approval.

R313-25-26. Environmental Monitoring.

(1) At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data shall cover at least a 12-month period.

(2) During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations shall be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and need for mitigative measures. The monitoring system shall be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

(3) After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system shall be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

(4) The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

R313-25-27. Alternative Requirements for Design and Operations.

The Executive Secretary may, upon request or on his own initiative, authorize provisions other than those set forth in R313-25-24 and 25-26 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of R313-25.

R313-25-28. Institutional Requirements.

(1) Land Ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the Federal or a State government.

(2) Institutional Control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and other equivalents as determined by the Executive Secretary, and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Executive Secretary, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

R313-25-30. Applicant Qualifications and Assurances.

The applicant shall show that it either possesses the necessary funds, or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

R313-25-31. Funding for Disposal Site Closure and Stabilization.

(1) The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including:

(a) decontamination or dismantlement of land disposal facility structures, and

(b) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on Executive Secretary approved cost estimates reflecting the Executive Secretary approved plan for disposal site closure and stabilization. The applicant's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

(2) In order to avoid unnecessary duplication and expense, the Executive Secretary will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other State agencies or local governmental bodies for decontamination, closure, and stabilization. The Executive Secretary will accept these arrangements only if they are considered adequate to satisfy the requirements of R313-25-31 and if they clearly identify that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

(3) The licensee's financial or surety arrangement shall be submitted annually for review by the Executive Secretary to assure that sufficient funds will be available for completion of the closure plan.

(4) The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that have already been accomplished, and other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

(5) The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Executive Secretary; the beneficiary, the site owner; and the principal, the licensee, not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee shall submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Executive Secretary, the beneficiary may collect on the original surety.

(6) Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on surety instruments.

(7) Financial or surety arrangements generally acceptable to the Executive Secretary include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or other types of arrangements as may be approved by the Executive Secretary. Self-insurance, or an arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

(8) The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Executive Secretary, and the license has been transferred to the site owner.

R313-25-32. Financial Assurances for Institutional Controls.

(1) Prior to the issuance of the license, the applicant shall provide for Executive Secretary approval, a binding arrangement, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and required maintenance during the institutional control period. The binding arrangement shall be reviewed annually by the Executive Secretary to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.

(2) Subsequent changes to the binding arrangement specified in R313-25-32(1) relevant to institutional control shall be submitted to the Executive Secretary for prior approval.

R313-25-33. Maintenance of Records, Reports, and Transfers.

(1) Licensees shall maintain records and make reports in connection with the licensed activities as may be required by the conditions of the license or by the rules and orders of the Executive Secretary.

(2) Records which are required by these rules or by license conditions shall be maintained for a period specified by the appropriate rules or by license condition. If a retention period is not otherwise specified, these records shall be maintained and transferred to the officials specified in R313-25-33(4) as a condition of license termination unless the Executive Secretary otherwise authorizes their disposition.

(3) Records which shall be maintained pursuant to R313-25 may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible

at the end of the required retention period.

(4) Notwithstanding R313-25-33(1) through (3), copies of records of the location and the quantity of wastes contained in the disposal site shall be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the State Governor, and other state, local, and federal governmental agencies as designated by the Executive Secretary at the time of license termination.

(5) Following receipt and acceptance of a shipment of waste, the licensee shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the condition of the waste packages as received, discrepancies between the materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and evidence of leakage or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and Executive Secretary regulations or rules. The licensee shall briefly describe repackaging operations of the waste packages included in the shipment, plus other information required by the Executive Secretary as a license condition.

(6) Licensees authorized to dispose of waste received from other persons shall file a copy of their financial report or a certified financial statement annually with the Executive Secretary in order to update the information base for determining financial qualifications.

(7)(a) Licensee authorized to dispose of waste received from other persons, pursuant to R313-25, shall submit annual reports to the Executive Secretary. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

(b) The reports shall include:

(i) specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year;

(ii) the results of the environmental monitoring program;

(iii) a summary of licensee disposal unit survey and maintenance activities;

(iv) a summary, by waste class, of activities and quantities of radionuclides disposed of;

(v) instances in which observed site characteristics were significantly different from those described in the application for a license; and

(vi) other information the Executive Secretary may require.

(c) If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report shall cover this specifically.

(8) In addition to the other requirements in R313-25-33, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

(a) The manifest information that must be electronically stored is:

(i) that required in Appendix G of 10 CFR 20.1001 to 20.2402, 1997 ed., which is incorporated into these rules by reference, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

(ii) that information required in R313-25-33(5).

(b) As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium.

R313-25-34. Tests on Land Disposal Facilities.

Licensees shall perform, or permit the Executive Secretary to perform, any tests the Executive Secretary deems appropriate or necessary for the administration of the rules in R313-25, including, but not limited to, tests of;

(1) wastes;

(2) facilities used for the receipt, storage, treatment, handling or disposal of wastes;

(3) radiation detection and monitoring instruments; or

(4) other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.

R313-25-35. Executive Secretary Inspections of Land Disposal Facilities.

(1) Licensees shall afford to the Executive Secretary, at reasonable times, opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed of.

(2) Licensees shall make available to the Executive Secretary for inspection, upon reasonable notice, records kept by it pursuant to these rules. Authorized representatives of the Executive Secretary may copy and take away copies of, for the Executive Secretary's use, any records required to be kept pursuant to R313-25.

KEY

radiation, radioactive waste disposal

Date of Enactment or Last Substantive Amendment

March 10, 2000

Notice of Continuation

October 10, 2001

Authorizing, Implemented, or Interpreted Law

19-3-104; 19-3-108

Rule converted into HTML by the Division of Administrative Rules.

For questions regarding the *content* or *application* of rules under Title R313, please contact the promulgating agency (Environmental Quality, Radiation Control). A list of agencies with links to their homepages is available at **http://www.utah.gov/government/agencylist.html**.

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Rule R313-26. Generator Site Access Permit Requirements for Accessing Utah Radioactive Waste Disposal Facllltles.

As in effect on September 1, 2002

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R313-26-1. Purpose and Scope.

The purpose of this rule is to establish procedures, criteria, and terms and conditions upon which the Executive Secretary issues permits to generators for accessing a land disposal facility located within the State. This rule also contains requirements for shippers. The requirements of Rule R313-26 are in addition to, and not in substitution for, other applicable requirements of these rules.

R313-26-2. Definitions.

As used in Rule R313-26, the following definitions apply:

"Broker" means a person who performs one or more of the following functions for a generator: arranges for transportation of the radioactive waste; collects or consolidates shipments of radioactive waste; or processes radioactive waste in some manner. "Broker" does not include a carrier whose sole function is to transport the radioactive waste.

"Disposal" means the isolation of wastes from the biosphere by placing them in a land disposal facility.

"Generator" means a person who:

(a) possesses any material or component:

(i) that contains radioactivity or is radioactively contaminated; and

(ii) for which the person foresees no further use; and

(b) transfers the material or component to:

(i) a commercial radioactive waste treatment or disposal facility; or

(ii) a broker.

"Generator Site Access Permit" means an authorization to deliver radioactive wastes to a land disposal facility located within the State.

"Land disposal facility" has the same meaning as that given in Section R313-25-2.

"Manifest" means the document, as defined in Appendix G of 10 CFR 20,used for identifying the quantity, composition, origin, and destination of radioactive waste during its transport to a disposal facility.

"Packager" means broker as defined in Section R313-26-2.

"Radioactive waste" means any material that contains radioactivity or is radioactively contaminated and is intended for ultimate disposal at a licensed land disposal facility in Utah.

"Shipper" means the person who offers radioactive waste for transportation, typically consigning this type of waste to a broker or land disposal facility.

R313-26-3. Generator Site Access Permits.

A generator or broker shall obtain a Generator Site Access Permit from the Executive Secretary before transferring radioactive waste to a land disposal facility in Utah.

(1) Generator Site Access Permit applications shall be filed on a form prescribed by the Executive Secretary.

(2) Applications shall be received by the Executive Secretary at least 30 days prior to any shipments being delivered to a land disposal facility in Utah.

(3) Each Generator Site Access Permit application shall include a certification to the Executive Secretary that the shipper shall comply with all applicable State or Federal laws, administrative rules and regulations, licenses, or license conditions of the land disposal facility regarding the packaging, transportation, storage, disposal and delivery of radioactive wastes.

(4) Generator Site Access Permit fees shall be assessed annually by the Executive Secretary based on the following classifications:

(a) Generators shipping more than 1000 cubic feet of radioactive waste annually to a land disposal facility in Utah.

(b) Generators shipping 1000 cubic feet or less of radioactive waste annually to a land disposal facility in Utah.

(c) Brokers shipping radioactive waste to a land disposal facility in Utah.

(5) Generator Site Access Permits shall be valid for a maximum of one year from the date of issuance. The Executive Secretary may modify individual Generator Site Access Permit terms and prorate the annual fees accordingly for administrative purposes.

(6) Generator Site Access Permits may be renewed by filing a new application with the Executive Secretary. To ensure timely renewal, generators and brokers shall submit applications, for Generator Site Access Permit renewal, a minimum of 30 days prior to the expiration date of their Generator Site Access Permit.

(7) Generator Site Access Permit fees are not refundable.

(8) Transfer of a Generator Site Access Permit shall be approved by the Executive Secretary.

(9) The number of Generator Site Access Permits required by each generator shall be determined by the following requirements:

(a) Generators who own multiple facilities within the same state may apply for one Generator Site Access Permit, provided the same contact person within the generator's company shall be responsible for responding to the Executive Secretary for matters pertaining to the waste shipments.

(b) Facilities which are owned by the same generator and located in different states shall obtain separate Generator Site Access Permits.

(c) Persons who both generate and broker wastes shall obtain separate Generator Site Access Permits.

R313-26-4. Shipper's Requirements.

(1) The shipper shall provide the Executive Secretary a copy of the Nuclear Regulatory Commission's "Uniform Low Level Radioactive Waste Manifest" for shipments consigned for disposal within Utah.

(2) The manifest shall be delivered to the Executive Secretary prior to the shipment arriving at the disposal site, but not more than thirty days prior to shipment departure.

(3) The generator's and broker's Generator Site Access Permit numbers shall be documented on the manifest.

(4) Generators and brokers shall ensure that all Generator Site Access Permits are current prior to shipment of waste to a land disposal facility located in the state, and that the waste will arrive at the land disposal facility prior to the expiration date of the Generator Site Access Permits.

(5) A broker shall ensure all radioactive waste contained within a shipment accepted for disposal at a land disposal facility in the state is traceable to the original generators and states, regardless of whether the waste is shipped directly from the point of generation to the disposal facility, or shipped through a broker.

R313-26-5. Land Disposal Facility Licensee Requirements.

The land disposal facility licensee shall ensure that generators and brokers have a current, unencumbered Generator Site Access Permit prior to accepting a generator's or broker's waste.

R313-26-6. Enforcement.

Generator Site Access Permittees shall be subject to the provisions of Rule R313-14 for violations of federal regulations, state rules or requirements in the current land disposal facility operating license regarding radioactive waste packaging, transportation, labeling, notification, classification, marking, manifesting or description.

KEY

radioactive waste generator permit

Date of Enactment or Last Substantive Amendment

September 14, 2001

Authorizing, Implemented, or Interpreted Law

19-3-106.4

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Rule R313-28. Use of X-Rays in the Healing Arts.

As in effect on September 1, 2002

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- **Authorizing, Implemented, or Interpreted Law**

R313-28-10. Purpose and Scope.

(1) The purpose of the rules in R313-28 is to prescribe the requirements for the use of x-rays in the healing arts.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-28-20. Definitions.

As used in R313-28, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Actual focal spot" refer to "Focal spot."

"Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"Assembler" means individuals engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent if they assemble components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having appropriate dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic EXPOSURE control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation. Phototimer and ion chamber devices are included in this category.

"Barrier" refer to "Protective barrier".

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means an x-ray system which has one or more certified components.

"Changeable filters" means filters designed to be removed by the operator.

"Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a population of observations.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for setting the technique factors.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" means computed tomography.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which house these components.

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of part of the human body for the purpose of recording or visualization for diagnostic purposes.

"Entrance EXPOSURE rate" means the EXPOSURE free in air per unit time at the point where the useful beam enters the patient.

"Equipment" refer to "X-ray equipment".

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes equipment housing, electrical interlocks, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

"Focal spot" means the area on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates. Also referred to as "Actual focal spot."

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer or HVL" means the thickness of specified material which attenuates the beam of radiation to an extent that the EXPOSURE rate is reduced to one-half of its original value. In this definition, the contribution of scatter radiation, other than that which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts screening" means the testing of a human population which is asymptomatic for the disease for which the screening is being performed. Excluded from this definition are those individuals whose risk factors for the disease are greater than for the population at large".

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds: for example, kVp times mA times seconds.

"HVL" refer to "half value layer."

"Image intensifier" means a device installed in its housing which instantaneously converts an x-ray pattern into a light image of higher energy density.

"Image receptor" means a device, for example, a fluorescent screen radiographic film, solid state detector, or gaseous detector, which transforms incident x-ray photons to produce a visible image or stores the information in a form which can be made into a visible image. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Irradiation" means the exposure of matter to ionizing radiation.

"Kilovolts peak" refer to "Peak tube potential".

"kV" means kilovolts.

"kVp" refer to "Peak tube potential."

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(a) the useful beam, and

(b) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum- rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, ten milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(c) For other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum- rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"mA" means tube current in milliamperes.

"mAs" means milliampere second or the product of the tube current in milliamperes and the time of exposure in seconds.

"Mammography imaging medical physicist" means an individual who conducts mammography surveys of mammography facilities.

"Mammography survey" means an evaluation of x-ray imaging equipment and oversight of a mammography facility's quality control program.

"Mobile x-ray equipment" refer to "X-ray equipment".

"Multiple scan average dose" means the average dose at the center of a series of scans, specified at the center of the axis of rotation of a CT x-ray system.

"New installation" means change, modification or relocation of new or existing shielding or equipment.

"Operator of diagnostic x-ray equipment" means either:

(a) The individual responsible for insuring that the appropriate technique factors are set on the x-ray equipment, or

(b) The individual who makes the radiation exposure.

"Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

"PBL" refer to "Positive beam limitation."

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"PID" refer to "Position indicating device."

"Portable x-ray equipment" refer to "X-ray equipment".

"Position indicating device (PID)" means a device, on dental x-ray equipment which indicates the beam position and establishes a definite source-surface (skin) distance. The device may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Primary beam scatter" means scattered radiation which has been deviated in direction or energy by materials irradiated by the primary beam.

"Primary protective barrier" refer to "Protective barrier".

"Protective apron" means an apron made of radiation absorbing materials, used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure.

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and for confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Rating" means the operating limits of an x-ray system or subsystem as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from x-ray photons.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the computer tomographic x-ray system between successive scans measured along the direction of such displacement.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction, energy or both direction and energy. Also refer to "Primary Beam Scatter".

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency at least that of the tube housing assembly.

"SID" refer to "Source-image receptor distance".

"Source" means the focal spot of the x-ray tube.

"Source to image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Special purpose x-ray system" means that which is designed for irradiation of specific body parts.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor, including a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"Stationary x-ray equipment" refer to "X-ray equipment".

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(c) For other equipment, peak tube potential in kV and either;

(i) the tube current in mA and exposure time in seconds, or

(ii) the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when they are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the switch or timer is activated.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"X-ray exposure control" means a device, switch, button, or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include associated equipment, for example, timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(b) "Portable" means x-ray equipment designed to be hand-carried.

(c) "Stationary" means x-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the EXPOSURE rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray tube" means an electron tube which is designed to be used primarily for the production of x- rays.

R313-28-31. General and Administrative Requirements.

(1) Persons shall not make, sell, lease, transfer, lend, or install x-ray equipment or the accessories used in connection with x-ray equipment unless the accessories and equipment, when properly placed in operation and properly used, will meet the applicable requirements of these rules.

(2) The registrant shall be responsible for directing the operation of the x-ray machines which are under the registrant's administrative control. The registrant or registrant's agent shall assure that the requirements of R313-28-31(2)(a) through R313-28-31(2)(i) are met in the operation of the x-ray machines.

(a) An x-ray machine which does not meet the provisions of these rules shall not be operated for diagnostic purposes, when directed by the Executive Secretary.

(b) Individuals who will be operating the x-ray equipment shall be instructed in the registrant's written radiation safety program and be qualified in the safe use of the equipment. Required operator qualifications are listed in R313-28-350.

(c) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and restrictions of the operating technique required for the safe operation of the x-ray systems. Individuals who operate x-ray systems shall be responsible for complying with these rules.

(d) Except for individuals who cannot be moved out of the room and the patient being examined, only the staff and ancillary personnel or other individuals needed for the medical procedure or training shall be present in the room during the radiographic exposure and shall be positioned as follows:

(i) individuals other than the patient shall be positioned so that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;

(ii) the x-ray operator, other staff, ancillary personnel and other individuals needed for the medical procedure shall be protected from primary beam scatter by protective aprons or barriers unless it can be shown that by virtue of distances employed, EXPOSURE levels are reduced to the limits specified in R313-15-201; and

(iii) patients who are not being examined and cannot be removed from the room shall be protected from the primary beam scatter by whole body protective barriers of not less than 0.25 mm lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and nearest edge of the image receptor.

(e) For patients who have not passed reproductive age, gonad shielding of not less than 0.5 mm lead equivalent material shall be used during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(f) Individuals shall not be exposed to the useful beam except for healing arts purposes unless the exposure has been authorized by a licensed practitioner of the healing arts. Deliberate exposures for the following purposes are prohibited:

(i) exposure of an individual for training, demonstration or other non-healing arts purposes; and

(ii) exposure of an individual for the purpose of healing arts screening except as authorized by R313-28-31(2)(i).

(g) When a patient or film must be provided with auxiliary support during a radiation exposure:

(i) mechanical holding devices shall be used when the technique permits. The written procedures, required by R313-28-31(2)(c), shall list individual projections where mechanical holding devices can be utilized;

(ii) written safety procedures, as required by R313-28-31(2)(c), shall indicate the requirements for selecting an individual to hold patients or films and the procedure that individual shall follow;

(iii) the individual holding patients or films during radiographic examinations shall be instructed in personal radiation safety and protected as required by R313-28-31(2)(d)(i);

(iv) Individuals shall not be used routinely to hold film or patients;

(v) In those cases where the patient must hold the film, except during intraoral examinations, portions of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and

(vi) Facilities shall have protective aprons and gloves available in sufficient numbers to provide protection to personnel who are involved with x-ray operations and who are otherwise not shielded.

(h) Personnel monitoring. Individuals who are associated with the operation of an x-ray system are subject to the applicable requirements of R313-15.

(i) Healing arts screening. Persons proposing to conduct a healing arts screening program shall not initiate the program without prior approval of the Executive Secretary or in the case of a research program, by an Investigational Review Board which has been approved by the United States Food and Drug Administration. When requesting approval, that person shall submit the information outlined in R313-28-400. If information submitted becomes invalid or outdated, the Executive Secretary shall be notified immediately.

(3) Maintenance of records and information. The registrant shall maintain at least the following information for each x-ray machine:

(a) model numbers of major components;

(b) record of surveys or calculations to demonstrate compliance with R313-15-302, calibration, maintenance and modifications performed on the x-ray machine; and

(c) a shielding design report for the x-ray suite which states assumed values for workload and use factors and includes a drawing of surrounding areas showing assumed values for occupancy factors.

(4) X-ray records. Facilities shall maintain an x-ray record containing the patient's name, the types of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. The registrant shall retain these records for three years after the record is made.

(5) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

(6) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for routine diagnostic radiological imaging, with the exception of standard film packets for intra-oral use in dental radiography. If the requirements of R313-28-31(6)(a) cannot be met, an exemption may be requested pursuant to R313-12-55.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) X-ray systems, other than fluoroscopic, computed tomography, dental or veterinary units, shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

R313-28-32. Plan Review.

(1) Prior to construction,the floor plans, shielding specifications and equipment arrangement of all

new installations, or modifications of existing installations, utilizing ionizing radiation shall be submitted to the Executive Secretary. The required information is denoted in R313-28-200 and R313-28-450.

(2) If the services of a consultant are used to review the shielding specifications, a copy of the report must be submitted to the Executive Secretary within 14 working days.

(3) The Executive Secretary may require additional modifications should a subsequent analysis of operating conditions, for example, a change in workload or use and occupancy factors, indicate the possibility of an individual receiving a dose in excess of the limits prescribed in R313-15.

R313-28-35. General Requirements for Diagnostic X-Ray Systems.

In addition to other requirements of R313-28, all diagnostic x-ray systems shall meet the following requirements:

(1) Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) Battery charge indicator. On battery powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 uC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors.

(4) Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.516 uC/kg (two milliroentgens) in one hour at five centimeters from accessible surfaces of the component when it is operated in an assembled x-ray system under the conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam quality.

(a) The half value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in R313-28-35, Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

DESIGN OPERATING RANGE (KILO VOLTS PEAK	MEASURED POTENTIAL (KILOVOLTS PEAK)	DENTAL INTRA-ORAL MANUFACTURED BEFORE AUGUST 1, 1974 AND ON OR AFTER DECEMBER 1, 1980	ALL OTHER DIAGNOSTIC X-RAY SYSTEMS
Below 51	30	(use prohibited)	0.3
	40	(use prohibited)	0.4
	50	1.5	0.5
	51	1.5	1.2

	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	? ?	? ?
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(b) For capacitor discharge equipment, compliance with the requirements of R313-28-35(5)(a) shall be determined with the system fully charged and a setting of 10 mAs for exposures.

(c) The required minimal half-value layer of the useful beam shall include the filtration contributed by materials which are permanently present between the focal spot of the tube and the patient.

(d) Filtration control. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by R313-28-35 (5)(a) is in the useful beam for the given kVp which has been selected.

(6) Multiple tubes. When two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. For equipment manufactured after August 1, 1974, indications shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(7) Mechanical support of tube head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement during exposure is a designed function of the x-ray system.

(8) Technique indicators.

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic EXPOSURE controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

(b) On equipment having fixed technique factors, the requirements, in R313-28-35(8)(a) may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(9) Maintaining compliance. Diagnostic x-ray systems and their associated components certified pursuant to the provisions of 21 CFR Part 1020 shall be maintained in compliance with applicable requirements of that standard.

(10) Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

(11) X-ray systems which have been granted a variance by the Director, Center for Devices and Radiological Health, Food and Drug Administration (Director), from the performance standards for ionizing radiation emitting products, in accordance with 21 CFR 1010.4, 1996 edition, shall be

deemed to satisfy the requirements in R313-28 that corresond to the variance granted by the Director. The registrant shall insure that labeling pursuant to CFR 1010.5(f) remains legible and visible on the x-ray system.

R313-28-40. Fluoroscopic X-Ray Systems.

All fluoroscopic x-ray systems used shall be image intensified and meet the following requirements:

(1) Primary barrier.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at SIDs for which the unit was designed.

(b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

(a) For certified fluoroscopic systems with or without a spot film device neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.

(b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully open, during fluoroscopy or spot filming, shall be no larger than the largest image receptor size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(c) For uncertified fluoroscopic systems without a spot film device, the requirements of R313-28-40(1) apply.

(d) Other requirements for fluoroscopic beam limitation:

(i) means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

(ii) equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

(iii) if provided, stepless adjustment shall at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

(iv) for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

(v) for non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

(a) means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Adjustments shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(b) neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent of the SID;

(c) it shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five by five centimeters;

(d) the center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

(e) on spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override the automatic x-ray field size adjustments required in R313-28-40(2) and (3), that means:

(a) shall be designed for use only in the event of system failure;

(b) shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(c) shall be clearly and durably labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

(5) Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure immediately, but means may be provided to permit completion of a single exposure of the series in process.

(6) Entrance EXPOSURE rate allowable limits.

(a) For fluoroscopic equipment manufactured before May 19, 1995, the following requirements apply:

(i) fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 2.58 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is provided. When so provided, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(ii) fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at combinations of tube potential and current which will result in a EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(iii) fluoroscopic equipment which is provided with both automatic exposure rate control and a manual mode shall not be operable at combinations of tube potential and current that will result in an exposure rate of 2.58 mC/kg (ten roentgens) per minute in either mode at the point where the center of the useful beam enters the patient except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is provided. When so provided, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements apply:

(i) fluoroscopic equipment operable at combinations of tube potential and current which will result in an EXPOSURE rate greater than 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control. Provision for manual selection of technique factors may be provided.

(ii) fluoroscopic equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 2.58 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient except:

(A) during recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in pulsed mode, or

(B) when an optional high level control is activated. When the high level control is activated, the

equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 5.16 mC/kg (20 roentgens) per minute at the point where the center of the useful beam enters the patient. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(c) Compliance with the requirements of R313-28-40(6) shall be determined as follows:

(i) if the source is below the x-ray table, the EXPOSURE rate shall be measured one centimeter above the tabletop or cradle;

(ii) if the source is above the x-ray table, the EXPOSURE rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(iii) for a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at available SID's, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly; or

(iv) for a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement. If the tabletop is movable, it shall be positioned as close as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the x-ray table.

(d) Fluoroscopic radiation therapy simulation systems are exempt from the requirements of R313-28- 40(6).

(7) Measurement of entrance EXPOSURE rates shall be performed for both maximum and typical values as follows:

(a) measurements shall be made annually or after maintenance of the system which might affect the EXPOSURE rate;

(b) results of these measurements shall be posted where the fluoroscopist may have ready access to the results while using the fluoroscope and in the record required in R313-28-31(3)(b). The measurement results shall be stated in roentgens per minute and include the machine settings used in determining results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results;

(c) conditions of the annual measurement of maximum entrance EXPOSURE rate shall be performed as follows:

(i) the measurement shall be made under the conditions that satisfy the requirements of R313-28- 40(6)(c);

(ii) the kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance EXPOSURE rate; and

(iii) x-ray systems that incorporate automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system;

and

(d) conditions of the annual measurement of typical entrance EXPOSURE rate are as follows:

(i) the measurement shall be made under the conditions that satisfy the requirements of R313-28- 40(6)(c);

(ii) the kVp, mA, and other selectable parameters shall be those settings typical of clinical use of the x-ray system; and

(iii) the x-ray system that incorporates automatic EXPOSURE rate control shall have an appropriate phantom placed in the useful beam to produce a milliamperage and kilovoltage typical of the use of the x-ray system.

(8) Barrier transmitted radiation rate limits.

(a) The EXPOSURE rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.516 uC/kg (two milliroentgens) per hour at ten centimeters from accessible surfaces of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance EXPOSURE rate.

(b) Measuring compliance of barrier transmission.

(i) The EXPOSURE rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(9) Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

(10) Source-skin distance. The source to skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(b) 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(c) 30 centimeters on all mobile fluoroscopes; or

(d) 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

(11) Fluoroscopic timer.

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of a preset cumulative on-time. The signal shall continue to sound while x-rays are produced until the timing device is reset.

(12) Control of scatter radiation.

(a) The tables of fluoroscopic assemblies when combined with normal operating procedures shall provide protection from scatter radiation so that unprotected parts of a staff or ancillary individual's body shall not be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

(b) Equipment configuration when combined with procedures shall not allow portions of a staff member's or ancillary person's body, except the extremities, to be exposed to unattenuated scattered radiation emanating from above the tabletop unless:

(i) the radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or self supporting curtains, in addition to the lead equivalency provided by the protective apron referred to in R313-28-31(2)(d),

(ii) that individual is at least 120 centimeters from the center of the useful beam, or

(iii) it is not feasible to attach shielding to special procedures equipment and personnel are wearing protective aprons.

(13) Spot film exposure reproducibility. Fluoroscopic systems equipped with radiographic spot film mode shall meet the exposure reproducibility requirements of R313-28-54.

(14) Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements R313-28-40(1), (8), and (11) provided that:

(a) the systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(b) the systems which do not meet the requirements of R313-28-40(11) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require, in these cases, that the timer be reset between examinations.

R313-28-51. Radiographic Systems Other than Fluoroscopic, Dental Intraoral, or Computed Tomography -- Beam Limitation.

The useful beam shall be limited to the area of clinical interest and show evidence of collimation. This shall be deemed to have been met if a positive beam limiting device meeting the manufacturer's specifications or the requirements of R313-28-300 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, for example, projections of the shutters of the collimator, cone cutting at the corners or a border at the film's edge.

(1) General purpose stationary and mobile x-ray systems.

(a) Only x-ray systems provided with a means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.

(b) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(c) The Board may grant an exemption on non-certified x-ray systems to R313-28-51(1)(a) and (b) provided the registrant makes a written application for the exemption and in that application:

(i) demonstrates it is impractical to comply with R313-28-51(1)(a) and (b); and

(ii) demonstrates the purpose of R313-28-51(1)(a) and (b) will be met by other methods.

(2) In addition to the requirements of R313-28-51(1) above, stationary general purpose x-ray systems, both certified and non-certified shall meet the following requirements:

(a) a method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

(b) the beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; and

(c) indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.

(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond the edges of the image receptor.

(4) Special purpose x-ray systems.

(a) Means shall be provided to limit the x-ray field in the plane of the image receptor so that the x-ray field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond the edges of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

(c) R313-28-51(4)(a) and R313-28-51(4)(b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in R313-28-51(1) or, when alignment means are also provided, may be met with either;

(i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the

requirements for the combination of image receptor sizes and SID's for which the unit is designed with the beam limiting device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for the combinations of image receptor sizes and SID's for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which the aperture is designed and shall indicate which aperture is in position for use.

R313-28-52. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography -- Radiation Exposure Control Devices.

(1) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, for example, the depression of a switch. Radiation exposure shall not be initiated without a deliberate action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(3) Manual Exposure Control: An x-ray control shall be incorporated into x-ray systems so that an exposure can be terminated at times except for:

(a) exposure of one-half second or less; or

(b) during serial radiography when means shall be provided to permit completion of a single exposure of the series in process.

(4) Automatic EXPOSURE controls, phototimers. When automatic EXPOSURE control is provided:

(a) indication shall be made on the control panel when this mode of operation is selected;

(b) when the x-ray tube potential is equal to or greater than 51 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than the interval equivalent to two pulses; and

(c) the minimum exposure time for all equipment other than that specified in R313-28-52(4)(b) shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater.

(5) Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(6) Exposure Duration, Timer, Linearity. For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliampere-seconds product obtained at two consecutive timer settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

(7) Exposure Control Location. The x-ray exposure control shall be placed so that the operator can view the patient while making the exposure.

(8) Operator Protection.

(a) Stationary x-ray systems shall be required to have the x-ray exposure switch permanently mounted in a protected area.

(b) Mobile and portable x-ray systems which are:

(i) used continuously for greater than one week at the same location, one room or suite, shall meet the requirements of R313-28-52(8)(a); or

(ii) used for less than one week at one location, one room, or suite shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

R313-28-53. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Source-to-Skin or Receptor Distance.

Mobile or portable radiographic systems shall be provided with a means to limit the source-to-skin distance to 30 or more centimeters.

R313-28-54. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Exposure Reproducibility.

When technique factors, including control panel selections associated with automatic exposure control systems, are held constant the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

R313-28-55. Radiographic Systems - Standby Radiation From Capacitor Discharge Equipment.

Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.516 uC/kg (two milliroentgens) per hour at five centimeters from accessible surfaces of the diagnostic source assembly, with the beam-limiting device fully open

R313-28-56. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Accuracy.

Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value for kVp and ten percent of the indicated value for times greater than 50 milliseconds.

R313-28-57. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- mA/mAs Linearity.

The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for fixed x-ray tube potentials within the range of 40 percent to 100 percent of the maximum rated potentials.

(1) Equipment having independent selection of x-ray tube current, mA. Where the tube current is

continuous, the average ratios of exposure to the indicated milliampere-seconds product, C/kg/mAs or mR/mAs, obtained at two consecutive tube current settings or at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(2) Equipment having a combined x-ray tube current-exposure time product, mAs, selector, but not a separate tube current, mA, selector. Where the tube current is continuous, the average ratios of exposure to the indicated milliampere-seconds product, C/kg/mAs or mR/mAs, obtained at two consecutive milliampere-seconds settings or at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

R313-28-80. Intraoral Dental Radiographic Systems.

In addition to the provisions of R313-28-31, R313-28-32 and R313-28-35, the requirements of this section apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in R313-28-51, R313-28-52 and R313-28-53. Intraoral dental radiographic systems used must meet the requirements of R313-28-80.

(1) Source-to-Skin distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(a) 18 centimeters if operable above 50 kilovolts peak, or

(b) 10 centimeters if not operable above 50 kilovolts peak.

(2) Field limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field so that:

(a) if the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; and

(b) if the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

(3) Exposure Initiation.

(a) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, for example, the depression of a switch. Radiation exposure shall not be initiated without a deliberate action; and

(b) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(4) Exposure Termination.

(a) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(b) An x-ray exposure control shall be incorporated into x-ray systems so that an exposure of more than 0.5 seconds can be terminated immediately by the operator.

(c) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(5) Exposure Indication. Means shall be provided for visual indication, observable from the operator's protected position, whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(6) Timer Linearity. For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliampere-seconds product obtained at two consecutive timer settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

(7) Exposure Control Location and Operator Protection.

(a) Stationary x-ray systems shall be required to have the x-ray exposure control mounted in a protected area or a means to allow the operator to be at least 2.7 meters (9.0 feet) from the tube housing assembly while making exposures; and

(b) Mobile and portable x-ray systems which are:

(i) used for greater than one week in the same location, for example, a room or suite, shall meet the requirements of R313-28-80(7)(a); or

(ii) used for less than one week in the same location shall be provided with either a protective barrier at least two meters high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

(8) Exposure Reproducibility. When all technique factors are held constant, the coefficient of variation of exposure shall not exceed 0.05 for certified x-ray systems or 0.10 for non-certified x-ray systems. This requirement applies to clinically used techniques.

(9) mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for fixed x-ray tube potentials within the range of 40 to 100 percent of the maximum rated potentials.

(a) For equipment having independent selection of x-ray tube current, the average ratios of exposure to the indicated milliampere-seconds product obtained at two consecutive tube current settings or, when the tube current selection is continuous, two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(b) For equipment having a combined x-ray tube current-exposure time product selector but not a separate tube current selector, the average ratios of exposure to the indicated milliampere-seconds product obtained at two consecutive mAs selector settings, or when the mAs selector provides continuous selection, at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(10) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed ten percent of the indicated value.

(11) Administrative Controls.

(a) Patient and film holding devices shall be used when the technique permits and holding is

required.

(b) The x-ray tube housing and the position indicating device shall not be hand-held during an exposure.

(c) The x-ray system shall be operated so that the useful beam at the patient's skin does not exceed the requirements of R313-28-80(2).

(d) Dental fluoroscopy without image intensification shall not be used.

R313-28-120. Mammography X-Ray Systems - Equipment Design and Performance Standards.

Only x-ray equipment meeting the following standards shall be used for mammography examinations.

(1) Equipment Design.

(a) FDA Standards. The requirements of 21 CFR 1020.30 and 21 CFR 1020.31, 1990 ed., are adopted and incorporated by reference.

(b) Dedicated Equipment. The x-ray equipment shall be specifically designed for mammography.

(c) Compression. Devices parallel to the imaging plane shall be available to immobilize and compress the breast during mammography procedures.

(d) Image Receptor. The x-ray equipment shall have both an 18 cm by 24 cm and a 24 cm by 30 cm image receptor and moving grids matched to each image receptor size.

(e) Automatic Exposure Control. X-ray equipment used in healing arts screening shall have automatic exposure control capabilities with a post exposure meter which indicates either milliampere-seconds or time values.

(f) Focal Spot. The focal spot size and source to image receptor distance configurations shall be limited to those appropriate for mammography.

(g) Beam Limitation. The x-ray equipment must allow for the x-ray field to extend to or beyond the chest wall edge of the image receptor.

(h) Magnification. X-ray equipment used in a noninvasive manner, requiring techniques beyond those utilized in standard mammography of asymptomatic patients, shall have x-ray magnification capability for noninvasive procedures. The equipment shall be able to provide at least one magnification within the range of 1.4 to 2.0.

(2) Performance Standards.

(a) State Standards. The x-ray equipment shall meet the applicable performance standards in R313- 28.

(b) Filtration. The useful beam shall have a half-value layer between the values of the measured kilovolts peak divided by 100 and the measured kilovolts peak divided by 100 plus 0.1 mm of aluminum equivalent. These values are to include the contribution to filtration by the compression

device.

(c) Minimum Radiation Output. X-ray equipment installed after the effective date of this rule shall meet the following standard: at 28 kilovolts peak on the focal spot used in routine healing arts screening the x-ray equipment shall be capable of sustaining a minimum output of 500 mR per second for at least three seconds. This output shall be measured at a point 4.5 centimeters from the surface of the patient support device when the source to image receptor distance is at its maximum and the compression paddle is in the beam. Existing x-ray equipment shall meet this minimum radiation output standard within one year of the effective date of this rule.

(d) Exposure Linearity. For kilovolts peak settings used clinically, the exposure per mAs shall be within plus or minus ten percent of the average exposure per mAs for those mAs stations or time stations, if applicable, that are tested.

(e) Automatic Exposure Control. The automatic exposure control mode shall produce consistent film density under changing patient and examination conditions. These conditions include breast thickness, adiposity, kilovolts peak and density settings. This requirement will be deemed satisfied when:

(i) an automatic exposure control technique guide is posted, and

(ii) for a series of films obtained for attenuator thicknesses of two to seven centimeters the resulting radiographic optical densities are within plus or minus 0.2 of the average value when the kVp and density control setting are adjusted as indicated on the technique guide. The attenuator used for determining compliance shall be either acrylic or other tissue equivalent material.

(f) Patient Dose. The x-ray equipment must be capable of giving an average glandular dose to an average size breast of average tissue density that does not exceed 3.0 mGy (0.3 rad) with a grid or 1.0 mGy (0.1 rad) without a grid. This will be deemed satisfied when using an acrylic phantom of 4.5 cm thickness. In addition, under all clinical use conditions, the average glandular dose to the breast must be less than 5.0 mGy (0.5 rad) per film for healing arts screening procedures.

(3) Mammography X-ray Equipment Quality Control.

(a) Initial Installation. Upon completion of the initial installation of the x-ray equipment, and before it is commissioned for clinical use, the equipment shall be evaluated by a mammography imaging medical physicist who has been approved by the Board. The evaluation results shall be submitted to the Executive Secretary for review and approval.

(b) Annual Evaluation. At intervals not to exceed 12 months or at the request of the Executive Secretary, the x-ray equipment shall be evaluated by a mammography imaging medical physicist who has been approved by the Board.

(c) The registrant shall develop and implement a quality control testing procedure for monitoring the radiation performance of the x-ray equipment.

R313-28-140. Qualifications of Mammography Imaging Medical Physicist.

An individual seeking certification by the Board for approval as a mammography imaging medical physicist shall file an application for certification on forms furnished by the Division. The Board may certify individuals who meet the requirements for initial qualifications. To remain certified by the Board as a mammography imaging medical physicist, an individual shall satisfy the requirements for continuing qualifications.

(1) Initial qualifications.

(a) Be certified by the American Board of Radiology in Radiological Physics or Diagnostic Radiological Physics, or the American Board of Medical Physicists in Diagnostic Imaging Physics; or

(b) Satisfy the following educational and experience requirements:

(i) Have a master's or higher degree from an accredited university or college in physical sciences; and

(ii) Have two years full-time experience conducting mammography surveys. Five mammography surveys shall be equal to one year full-time experience.

(2) Continuing qualifications.

(a) During the three-year period after certification, the individual shall earn 15 hours of continuing educational credits in mammography imaging; and

(b) Perform at least two mammography surveys annually.

(3) Mammography imaging medical physicists who fail to maintain the required continuing qualifications stated in R313-28-140(2) shall re-establish their qualifications before independently surveying another mammography facility. To re-establish their qualifications, mammography imaging physicists who fail to meet:

(a) The continuing education requirements of R313-28-140(2)(a) must obtain a sufficient number of continuing educational credits to bring their total credits up to the required 15 in the previous three years.

(b) The continuing experience requirement of R313-28-140(2)(b) must obtain experience by surveying two mammography facilities for each year of not meeting the continuing experience requirements under the supervision of a mammography imaging medical physicist approved by the Board.

R313-28-160. Computed Tomography X-ray Equipment.

(1) Equipment Requirements.

(a) In the event of equipment failure affecting data collection, means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or intercepting the x-ray beam with a shutter mechanism through the use of either a back-up timer or devices which monitor equipment function.

(b) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by R313-28-160 (1)(a).

(c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans, of greater than 0.5 second duration.

(2) Tomographic Plane Indication and Alignment.

(a) Means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic plane.

(b) If a device using a light source is used to satisfy R313-28-160 (2)(a), the light source shall provide illumination at levels sufficient to permit visual determination of the location of the tomographic plane or reference plane.

(c) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(3) Beam-On and Shutter Status Indicators.

(a) The computed tomography (CT) x-ray control panel and CT gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(b) Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT Conditions of Operation.

(a) The CT x-ray system shall be designed such that technique factors, tomographic section thickness, and scan increment shall be indicated prior to the initiation of a scan or series of scans.

(5) Quality Assurance Procedures. Quality assurance procedures shall be conducted on the CT x-ray equipment.

(a) The quality assurance procedures shall be in writing. Such procedures shall include, but not be limited to, the following:

(i) Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

(ii) Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

(b) The parameters measured to satisfy R313-28-160(5)(a)(ii) shall include, but not be limited to, kVp, mA and reproducibility of dose appropriate to the type of CT procedures performed.

(c) Records of tests performed to satisfy the requirements of R313-28-160(5)(a) and (b) shall be maintained for three years for inspection by the Division.

(6) Dose Calibration.

(a) Radiation measurements shall be performed at least annually and after change or replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation measuring instrument shall be traceable to a national standard and shall be calibrated at intervals not to exceed two years.

(c) Measurements shall be specified in terms of the multiple scan average dose, using phantoms and technique factors appropriate to the type of CT procedures performed.

R313-28-200. Information on Radiation Shielding Required for Plan Reviews.

In order to evaluate a need for radiation shielding associated with a plan review, the following information must be submitted.

(1) The plans showing, as a minimum, the following:

(a) the normal location of the radiation producing equipment's radiation port, the port's travel and traverse limits, general directions of the radiation beam, locations of windows, the location of the operator's booth, and the location of the x-ray control panel;

(b) structural composition and thickness of walls, doors, partitions, floor, and ceiling of the rooms concerned;

(c) the dimensions, including height, floor to floor, of the rooms concerned;

(d) the type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest existing occupied areas;

(e) the make and model of the x-ray equipment, the maximum energy output, and the energy waveform; and

(f) the type of examination or treatment which will be performed with the equipment.

(2) Information on the anticipated workload of the x-ray systems in mA-minutes per week.

(3) A report showing all basic assumptions used in the development of the shielding specifications.

R313-28-300. Additional Requirements Applicable to Certified Systems Only.

Diagnostic x-ray systems incorporating one or more certified components shall be required to comply with the following additional requirements which relate to the certified component.

(1) Beam limitation for stationary and mobile general purpose x-ray systems.

(a) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(b) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 LUX (15 foot-candles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of the quadrants of the light field. Radiation therapy simulation systems are exempt from this requirement.

(2) Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the additional field limitation requirements of R313-28-51(1) or R313-28-300(1).

(3) Beam limitation and alignment on stationary general purpose x-ray systems equipped with PBL.

(a) PBL shall prevent the production of x-rays when:

(i) either the length or the width of the x-ray field in the plane of the image receptor differs, except as permitted by R313-28-300(3)(c), from the corresponding image receptor dimensions by more than three percent of the SID; or

(ii) the sum of the length and width differences as stated in R313-28-300(3)(a)(i) without regard to sign exceeds four percent of the SID.

(b) Compliance with R313-28-300(3)(a) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

(c) The PBL system shall be capable of operation, at the discretion of the operator, so that the field size at the image receptor can be adjusted to a size smaller than the image receptor through stepless adjustment of the field size. The minimum field size at a distance of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(d) The PBL system shall be designed so that if a change in image receptor does not cause an automatic return to PBL function as described in R313-28-300(3)(a), then change of the image receptor size or SID must cause the automatic return.

(4) Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

R313-28-350. Qualifications of Operators.

Operators of diagnostic x-ray systems must be licensed to practice in Utah in accordance with Title 58 Chapter 54.

(1) The registrant shall document that the operator of diagnostic x-ray equipment is trained in the proper choice of technique factors to be used and in the safe and effective operation of the x-ray equipment.

R313-28-400. Information to be Submitted by Persons Proposing to Conduct Healing Art Screening.

Individuals requesting that the Executive Secretary approve a healing arts screening program shall submit the following information for evaluation:

(1) name and address of the applicant and, where applicable, the names and addresses of agents within this State;

(2) diseases or conditions for which the x-ray examinations are to be used;

(3) description, in detail, of the x-ray examinations proposed in the screening program including the frequency of screening and the duration of the entire screening program;

(4) description of the population to be examined in the screening program including age, sex, physical condition, and other appropriate information; and

(5) an evaluation of known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

R313-28-450. Minimum Design Requirements for an X-ray Machine Operator's Booth - New Installations Only.

(1) Space requirements:

(a) The operator shall be allotted not less than 0.70 square meter (7.5 square feet) of unobstructed floor space in the booth.

(b) The minimum space as indicated above may be geometric configurations with no dimension of less than 0.61 meters (two feet).

(c) The space shall be allotted excluding encumbrances by the console, for example, overhang or cables, or other similar encroachments.

(d) The booth shall be located or constructed to ensure that unattenuated primary beam scatter originating on the examination table or at the wall mounted image receptor will not reach the operator's position in the booth.

(2) Structural Requirements.

(a) The booth walls shall be permanently fixed barriers of at least 2.13 meters (seven feet) high.

(b) When a door or movable panel is used as an integral part of the booth shielding, it must have a permissive device which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of R313-15.

(3) X-Ray Exposure Control Placement: The x-ray exposure control for the system shall be fixed within the booth and:

(a) shall be at least one meter (40 inches) from points subject to primary beam scatter, leakage or primary beam radiation; and

(b) shall allow the operator to use the majority of the available viewing windows.

(4) Viewing system requirements:

(a) When the viewing system is a window:

(i) the viewing window shall have a visible area of at least 0.09 square meters (one square foot);

(ii) regardless of size or shape, at least 0.09 square meters (one square foot) of the window area must be centered no less than 0.6 meters (two feet) from the open edge of the booth and no less than 1.5 meters (five feet) from the floor; and

(iii) the window shall have at least the same lead equivalence of that required in the booth's wall in which it is mounted.

(b) When the viewing system is by mirrors, the mirrors shall be so located as to accomplish the general requirements of R313-28-450(4)(a).

(c) When the viewing system is by electronic means:

(i) the camera shall be so located as to accomplish the general requirements of R313-28-450(4)(a); and

(ii) there shall be an alternate viewing system as a backup for the primary system.

KEY

dental, x-ray, mammography, beam limitation

Date of Enactment or Last Substantive Amendment

December 14, 2001

Notice of Continuation

October 10, 2001

Authorizing, Implemented, or Interpreted Law

19-3-104

DAR File No. 24109
This filing was published in the 11/01/2001, issue, Vol. 2001, No.21, of the Utah State Bulletin.

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Environmental Quality, Radiation Control

R313-28-31

General and Administrative Requirements

NOTICE OF PROPOSED RULE
DAR File No.: 24109
Filed: 10/12/2001, 09:36
Received by: NL

RULE ANALYSIS

Purpose of the rule or reason for the change:
This rule is being changed to clarify a requirement involving the use of mechanical holding devices. Various devices are sometimes used to support a patient or X-ray film during a radiation exposure.

Summary of the rule or change:
The rule is being changed so that written procedures must contain a list of individual projections where mechancial holding devices can be used instead of a list of projections where holding devices cannot be utilized.

State statutory or constitutional authorization for this rule:
Sections 19-3-104 and 19-3-108

Anticipated cost or savings to:
the state budget:
There is no anticipated cost or savings to the State budget as this clarification to the rule does not have a fiscal impact on the State budget.

local governments:
There will not be a cost or savings to local government as local government is not affected by this rulemaking.

other persons:
There may be an insignificant cost savings for affected persons. This is because any list of procedures where mechanical holding devices can be utilized is inherently smaller than any list of

procedures where mechanical holding devices cannot be used.

Compliance costs for affected persons:
There may be an insignificant cost savings for affected persons. This is because any list of procedures where mechanical holding devices can be utilized is inherently smaller than any list of procedures where mechanical holding devices cannot be used.

Comments by the department head on the fiscal impact the rule may have on businesses:
The fiscal impact of this rule may allow registrants to realize small savings as they develop written radiation safety procedures.

The full text of this rule may be inspected, during regular business hours, at the Division of Administrative Rules, or at:
Environmental Quality
Radiation Control
168 N 1950 W
SALT LAKE CITY UT 84116-3085

Direct questions regarding this rule to:
Craig Jones at the above address, by phone at 801-536-4264, by FAX at 801-533-4097, or by Internet E-mail at cjones@deq.state.ut.us

Interested persons may present their views on this rule by submitting written comments to the address above no later than 5:00 p.m. on:
12/03/2001

This rule may become effective on:
12/14/2001

Authorized by:
William Sinclair, Director

RULE TEXT

R313. Environmental Quality, Radiation Control.

R313-28. Use of X-Rays in the Healing Arts.

R313-28-31. General and Administrative Requirements.

(1) Persons shall not make, sell, lease, transfer, lend, or install x-ray equipment or the accessories used in connection with x-ray equipment unless the accessories and equipment, when properly placed in operation and properly used, will meet the applicable requirements of these

rules.

(2) The registrant shall be responsible for directing the operation of the x-ray machines which are under the registrant's administrative control. The registrant or registrant's agent shall assure that the requirements of R313-28-31(2)(a) through R313-28-31(2)(i) are met in the operation of the x-ray machines.

(a) An x-ray machine which does not meet the provisions of these rules shall not be operated for diagnostic purposes, when directed by the Executive Secretary.

(b) Individuals who will be operating the x-ray equipment shall be instructed in the registrant's written radiation safety program and be qualified in the safe use of the equipment. Required operator qualifications are listed in R313-28-350.

(c) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and restrictions of the operating technique required for the safe operation of the x-ray systems. Individuals who operate x-ray systems shall be responsible for complying with these rules.

(d) Except for individuals who cannot be moved out of the room and the patient being examined, only the staff and ancillary personnel or other individuals needed for the medical procedure or training shall be present in the room during the radiographic exposure and shall be positioned as follows:

(i) individuals other than the patient shall be positioned so that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;

(ii) the x-ray operator, other staff, ancillary personnel and other individuals needed for the medical procedure shall be protected from primary beam scatter by protective aprons or barriers unless it can be shown that by virtue of distances employed, EXPOSURE levels are reduced to the limits specified in R313-15-201; and

(iii) patients who are not being examined and cannot be removed from the room shall be protected from the primary beam scatter by whole body protective barriers of not less than 0.25 mm lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and nearest edge of the image receptor.

(e) For patients who have not passed reproductive age, gonad shielding of not less than 0.5 mm lead equivalent material shall be used during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(f) Individuals shall not be exposed to the useful beam except for healing arts purposes unless the exposure has been authorized by a licensed practitioner of the healing arts. Deliberate exposures for the following purposes are prohibited:

(i) exposure of an individual for training, demonstration or other non-healing arts purposes; and

(ii) exposure of an individual for the purpose of healing arts screening except as

authorized by R313-28-31(2)(i).

(g) When a patient or film must be provided with auxiliary support during a radiation exposure:

(i) mechanical holding devices shall be used when the technique permits. The written procedures, required by R313-28-31(2)(c), shall list individual projections where mechanical holding devices can[~~not~~] be utilized;

(ii) written safety procedures, as required by R313-28-31(2)(c), shall indicate the requirements for selecting an individual to hold patients or films and the procedure that individual shall follow;

(iii) the individual holding patients or films during radiographic examinations shall be instructed in personal radiation safety and protected as required by R313-28-31(2)(d)(i);

(iv) Individuals shall not be used routinely to hold film or patients;

(v) In those cases where the patient must hold the film, except during intraoral examinations, portions of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and

(vi) Facilities shall have protective aprons and gloves available in sufficient numbers to provide protection to personnel who are involved with x-ray operations and who are otherwise not shielded.

(h) Personnel monitoring. Individuals who are associated with the operation of an x-ray system are subject to the applicable requirements of R313-15.

(i) Healing arts screening. Persons proposing to conduct a healing arts screening program shall not initiate the program without prior approval of the Executive Secretary or in the case of a research program, by an Investigational Review Board which has been approved by the United States Food and Drug Administration. When requesting approval, that person shall submit the information outlined in R313-28-400. If information submitted becomes invalid or outdated, the Executive Secretary shall be notified immediately.

(3) Maintenance of records and information. The registrant shall maintain at least the following information for each x-ray machine:

(a) model numbers of major components;

(b) record of surveys or calculations to demonstrate compliance with R313-15-302, calibration, maintenance and modifications performed on the x-ray machine; and

(c) a shielding design report for the x-ray suite which states assumed values for workload and use factors and includes a drawing of surrounding areas showing assumed values for occupancy factors.

(4) X-ray records. Facilities shall maintain an x-ray record containing the patient's name,

the types of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. The registrant shall retain these records for three years after the record is made.

(5) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

(6) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for routine diagnostic radiological imaging, with the exception of standard film packets for intra-oral use in dental radiography. If the requirements of R313-28-31 (6)(a) cannot be met, an exemption may be requested pursuant to R313-12-55.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) X-ray systems, other than fluoroscopic, computed tomography, dental or veterinary units, shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

KEY: dental, x-ray, mammography, beam limitation

[~~December 8, 2000~~]2001

Notice of Continuation May 1, 1997

19-3-104

ADDITIONAL INFORMATION

PLEASE NOTE:

- Text to be deleted is struck through and surrounded by brackets (e.g., [~~example~~]). Text to be added is underlined (e.g., example). Some browsers may not depict some or any of these attributes on the screen or when the document is printed.
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Rule R313-30. Therapeutic Radiation Machines.

As in effect on September 1, 2002

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R313-30-1. Scope and Applicability.

(1) R313-30 establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of R313-30 are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established by R313-30-3(3).

(3) R313-30 shall only apply to therapeutic radiation machines which accelerate electrons into a target to produce bremsstrahlung or which accelerate electrons to produce a clinically useful electron beam.

R313-30-2. Definitions.

As used in R313-30, the following definitions apply:

"Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accessible surfaces" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool, or without opening an access panel or door.

"Added filtration" means filtration which is in addition to the inherent filtration.

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"Barrier" See "Protective barrier."

"Beam axis" means the axis of rotation of the radiation head.

"Beam-limiting device" means a field defining collimator which provides a means to restrict the dimensions of the useful beam.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Changeable filters" means filters, exclusive of inherent filtration, which can be removed from the useful beam through electronic, mechanical, or physical processes.

"Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

"Detector" See "Radiation detector."

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to R313-30-6.

"Gantry" means that part of a therapeutic radiation machine supporting and allowing movements of the radiation head about a center of rotation.

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. Note that 1 Gy equals 100 rad.

"Half-value layer (HVL)" means the thickness of a specified material which attenuates x-radiation or gamma radiation to the extent that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

"Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Kilovolt (kV) or kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

"Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

"Leakage radiation" means radiation emanating from the therapeutic radiation machine except for the useful beam.

"Light field" means the area illuminated by light, simulating the radiation field.

"mA" means milliampere.

"Megavolt (MV) or mega electron volt (MeV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

"Monitor unit (MU)" See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

"Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Phantom" means an object which attenuates, absorbs, and scatters ionizing radiation in the same quantitative manner as tissue.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

"Primary protective barrier" See "Protective barrier."

"Protective barrier" means a barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam or a barrier which attenuates the primary beam.

(b) "Secondary protective barrier" means the material which attenuates stray radiation.

"Radiation detector" means a device which, in the presence of radiation provides, by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation field" See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation Therapy Physicist" means an individual qualified in accordance with R313-30-3(4).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Secondary protective barrier" See "Protective barrier."

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"Sievert (Sv)" means the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert. Note that 1 Sv equals 100 rem.

"Simulator, or radiation therapy simulation system" means an x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Source" means the region or material from which the radiation emanates.

"Source-skin distance (SSD)" See "Target-skin distance."

"Stationary beam radiation therapy" means radiation therapy without displacement of the radiation source relative to the patient during irradiation.

"Stray radiation" means the sum of leakage and scattered radiation.

"Target" means that part of an x-ray tube or particle accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient.

"Tenth-value layer (TVL)" means the thickness of a specified material which, x-radiation or gamma radiation to the extent that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements that are contained within the tube

housing.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

"Virtual source" means a point from which radiation appears to originate.

"Wedge filter" means a filter which effects continuous change in transmission over all or a part of the radiation field.

"X-ray tube" means an electron tube which is designed to be used primarily for the production of x- rays.

R313-30-3. General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Department. The registrant or the registrant's agent shall ensure that the requirements of R313-30 are met in the operation of the therapeutic radiation machines.

(2) A therapeutic radiation machine which does not meet the provisions of these rules shall not be used for irradiation of patients.

(3) Training for External Beam Radiation Therapy Authorized Users. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall require the authorized user to be a physician who:

(a) Is certified in:

(i) Radiology or therapeutic radiology by the American Board of Radiology; or

(ii) Radiation oncology by the American Osteopathic Board of Radiology; or

(iii) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(iv) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(i) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology.

(ii) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

(A) Review of the full calibration measurements and periodic quality assurance checks;

(B) Preparing treatment plans and calculating treatment times;

(C) Using administrative controls to prevent misadministrations;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and

(E) Checking and using radiation survey meters.

(iii) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(A) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and limitations and contraindications;

(B) Selecting proper dose and how it is to be administered;

(C) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(D) Post-administration follow-up and review of case histories.

(iv) An individual who satisfies the requirements in R313-30-3(b), but not R313-30-3(a), must submit an application to the Executive Secretary and must satisfy the requirements in R313-30-3 (a) within one year of initial application to the Executive Secretary.

(c) After December 31, 1994, a physician shall not act as an authorized user for a therapeutic radiation machine until the physician's training has been reviewed and approved by the Executive Secretary.

(4) Training for Radiation Therapy Physicist. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall require the Radiation Therapy Physicist to:

(a) Satisify the provisions of R313-16, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

(b) Be certified by the American Board of Radiology in:

(i) Therapeutic radiological physics; or

(ii) Roentgen-ray and gamma-ray physics; or

(iii) X-ray and radium physics; or

(iv) Radiological physics; or

(c) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(d) Be certified by the Canadian College of Medical Physics; or

(e) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in R313-30-4(1), R313-30-6(16), R313-30-7(19), R313-30- 6(17), and R313-30-7(20) under the supervision of a Radiation Therapy Physicist during the year of work experience.

(f) Notwithstanding the provisions of R313-30-3(4)(e), certification pursuant to R313-30-3(4)(b), (c) or (d) shall be required on or before December 31, 1999 for all persons currently qualifying as a Radiation Therapy Physicist pursuant to R313-30-3(4)(e).

(5) Qualifications of Operators.

(a) Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists.

(b) The names and training of personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(6) Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be available in the control area of a therapeutic radiation machine, including restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be familiar with these rules as required in R313-18- 12(1)(c).

(7) Individuals shall not be exposed to the useful beam except for medical therapy purposes. Exposure for medical therapy purposes shall be ordered in writing by an authorized user who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

(8) Visiting Authorized User. Notwithstanding the provisions of R313-30-3(7), a registrant may permit a physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

(a) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee; and

(b) The visiting authorized user meets the requirements established for authorized users in R313-30- 3(3)(a) and R313-30-3(3)(b); and

(c) The registrant maintains copies of records specified by R313-30-3(8) for five years from the date of the last visit.

(9) Individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of R313-30, these individuals are also subject to the requirements of R313-15-201, R313-15-202, R313-15-205 and R313-15- 502.

(10) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for therapeutic radiation machines, for inspection by the representatives of the Executive Secretary:

(a) Report of acceptance testing;

(b) Records of surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by R313-30, as well as the names of persons who performed the activities;

(c) Records of major maintenance and modifications performed on the therapeutic radiation machine after the effective date of these rules, as well as the names of persons who performed the services; and

(d) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(11) Records Retention. Records required by R313-30 shall be retained until disposal is authorized by the Executive Secretary unless another retention period is specifically authorized in R313-30. Required records shall be retained in an active file from at least the time of generation until the next inspection by a representative of the Executive Secretary. A required record generated prior to the last inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until the Executive Secretary authorizes final disposal.

R313-30-4. General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

(1) Protection Surveys.

(a) The registrant shall ensure that radiation protection surveys of new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with R313-30-8. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM- ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(i) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in R313-15-201(1); and

(ii) Radiation levels in unrestricted areas do not exceed the limits specified in R313-15-301(1).

(b) In addition to the requirements of R313-30-4(1)(a), a radiation protection survey shall also be performed prior to subsequent medical use and:

(i) After making changes in the treatment room shielding;

(ii) After making changes in the location of the therapeutic radiation machine within the treatment room;

(iii) After relocation of, or modification of, the therapeutic radiation machine; or

(iv) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(c) The survey record shall indicate instances where the facility, in the opinion of the Radiation Therapy Physicist or a Certified Health Physicist, is in violation of applicable radiation protection rules. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instruments used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in areas expressed in microsieverts, millirems, per hour, the calculated maximum level of radiation over a period of one week for restricted and unrestricted areas, and the signature of the individual responsible for conducting the survey;

(d) If the results of the surveys required by R313-30-4(1)(a) or R313-30-4(1)(b) indicate radiation levels in excess of the respective limit specified in R313-30-4(1)(a), the registrant shall lock the control in the "OFF" position and not use the unit:

(i) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(ii) Until the registrant has received a specific exemption from the Board.

(2) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by R313-30-4(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by R313-15-301(1) of these rules, before beginning the treatment program the registrant shall:

(a) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with R313-15-301(1) of these rules;

(b) Perform the survey required by R313-30-4(1) again; and

(c) Include in the report required by R313-30-4(4) the results of the initial survey, a description of the modification made to comply with R313-30-4(2)(a), and the results of the second survey; or

(d) Request and receive a registration amendment under R313-15-301(3) of these rules that authorizes radiation levels in unrestricted areas greater than those permitted by R313-15-301(1) of these rules.

(3) Possession of Survey Instruments. Facility locations authorized to use a therapeutic radiation machine in accordance with R313-30-6 and R313-30-7 shall possess appropriately calibrated portable monitoring equipment. As a minimum, the equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 uSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with R313-30-8.

(4) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 shall furnish a copy of the records required in R313-30-4(1) and R313-30-4(2) to the Executive Secretary within 30 days following completion of the action that initiated the record requirement.

R313-30-5. Quality Management Program.

(1) In addition to the definitions in R313-30-2, the following definitions are applicable to a quality management program:

"Course" means the entire treatment consisting of multiple fractions as prescribed in the written directive.

"Misadministration" means the administration of an external beam radiation therapy dose:

(a) Involving the wrong patient, wrong treatment modality, or wrong treatment site;

(b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;

(c) When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

"Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

"Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

(2) Scope and Applicability. Applicants or registrants subject to R313-30-6 or R313-30-7 shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) Prior to administration, a written directive is prepared for an external beam radiation therapy dose;

(i) Notwithstanding R313-30-5(2)(a), a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

(ii) Notwithstanding R313-30-5(2)(a), if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is

documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(iii) Notwithstanding R313-30-5(2)(a), if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.

(b) Prior to the administration of a course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

(c) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

(d) An administration is in accordance with the written directive; and

(e) Unintended deviations from the written directive is identified and evaluated, and appropriate action are taken.

(3) Development of Quality Management Program.

(a) An application for registration subject to R313-30-6 or R313-30-7 shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by R313-16 of these rules. The registrant shall implement the program upon issuance of a Certificate of Registration by the Executive Secretary;

(b) Existing registrants subject to R313-30-6 or R313-30-7 shall submit to the Executive Secretary a written certification that a quality management program has been implemented by December 31, 1994.

(4) As a part of the quality management program, the registrant shall:

(a) Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, recordable events, and misadministrations to verify compliance with the quality management program;

(b) Conduct these reviews annually. The intervals should not exceed 12 months and shall not exceed 13 months;

(c) Evaluate these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of R313-30-5(2); and

(d) Maintain records of these reviews, including the evaluations and findings of the reviews, in a form that can be readily audited, for three years.

(5) The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to recordable events by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what corrective actions are required to prevent recurrence; and

(c) Retaining a record, in a form that can be readily audited, for three years, of the relevant facts and what corrective actions were taken.

(6) The registrant shall retain:

(a) Written directives; and

(b) A record of administered radiation doses, in a form that can be readily audited, for three years after the date of administration.

(7) The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(8) The registrant shall evaluate misadministrations and shall take the following actions in response to a misadministration:

(a) Notify the Executive Secretary by telephone no later than the next calendar day after discovery of the misadministration;

(b) Submit a written report to the Executive Secretary within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian, this person will subsequently be referred to as "the patient," and if not, why not; and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

(c) Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the physician will inform the patient, or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible thereafter. The registrant shall not delay appropriate medical care for the patient, including necessary remedial care as a result of the misadministration, because of a delay in notification;

(d) Retain a record of misadministrations for five years. The record shall contain the names of individuals involved; including the prescribing physician, allied health personnel, the patient, and the patient's referring physician; the patient's social security number or identification number if one has been assigned; a brief description of the event; why it occurred; the effect on the patient; what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence; and

(e) If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the Executive Secretary, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the Executive Secretary can be obtained from the registrant;

(9) Aside from the notification requirement, nothing in R313-30-5(8) affects the rights or duties

of registrants and physicians in relation to patients, the patient's responsible relatives or guardians, or to others.

R313-30-6. Therapeutic Radiation Machines of Less Than 500 kV.

(1) Leakage Radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(a) Systems 5-50 kV. The leakage air kerma rate measured at a position five centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in one hour.

(b) Systems greater than 50 and less than 500 kV. The leakage air kerma rate measured at a distance of one meter from the source in every direction shall not exceed 1 cGy (1 rad) in one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

(2) Permanent Beam Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or Removable Beam Limiting Devices.

(a) Adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used;

(b) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter System. The filter system shall be so designed that:

(a) Filters can not be accidentally displaced at every possible tube orientation;

(b) For equipment installed after the effective date of these rules, an interlock system prevents irradiation if the proper filter is not in place;

(c) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one meter under operating conditions; and

(d) Filters shall be marked as to its material of construction and its thickness.

(5) Tube Immobilization.

(a) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

(b) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and the marking shall be readily

accessible for use during calibration procedures.

(7) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(a) A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector. The timer shall activate with an indication of "BEAM-ON" and retain its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer;

(b) For equipment manufactured after the effective date of these rules, the timer shall be a cumulative timer with an elapsed time indicator. Otherwise, the timer may be a countdown timer;

(c) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring system present has not previously terminated irradiation;

(d) The timer shall permit pre-setting and determination of exposure times as short as one second;

(e) The timer shall not permit an exposure if set at zero;

(f) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(g) Timer shall be accurate to within one percent of the selected value or to within one second, whichever is greater.

(9) Control Panel Functions. The control panel, in addition to the displays required by other provisions in R313-30-6, shall have:

(a) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(b) An indication of whether x-rays are being produced;

(c) Means for indicating x-ray tube potential and current;

(d) The means for terminating an exposure at any time;

(e) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(f) For therapeutic radiation machines manufactured after the effective date of these rules, a positive display of specific filters in the beam.

(10) Multiple Tubes. When a control panel may energize more than one x-ray tube:

(a) It shall be possible to activate only one x-ray tube at a time;

(b) There shall be an indication at the control panel identifying which x-ray tube is activated; and

(c) There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-Skin Distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low Filtration X-ray Tubes. Therapeutic radiation machines equipped with a beryllium or other low-filtration window shall have a label clearly marked on the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(14) Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of R313-30-9, the treatment room shall meet the following design requirements:

(a) Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

(b) Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(15) Additional Requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(a) Protective barriers shall be fixed except for entrance doors or beam interceptors;

(b) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(c) Interlocks shall be provided so that entrance doors, including doors to interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by a door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(d) When a door referred to in R313-30-6(15)(c) is opened while the x-ray tube is activated, the irradiation shall be interrupted either electrically or by the closure of the shutter.

(16) Full Calibration Measurements.

(a) Full calibration of a therapeutic radiation machine subject to R313-30-6 shall be performed

by, or under the direct supervision of, a Radiation Therapy Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(ii) Annually. The intervals should not exceed 12 months and shall not exceed 13 months; and

(iii) Before medical use under the following conditions:

(A) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(B) Following a component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(iv) Notwithstanding the requirements of R313-30-6(16)(a)(iii):

(A) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and energies that are not within their acceptable range; and

(B) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in R313-30-6(16)(a)(iii)(A).

(v) The registrant shall use the dosimetry system described in R313-30-8(6)(a) to perform the full calibration required in R313-30-6(16)(b);

(b) To satisfy the requirement of R313-30-6(16)(a), full calibration shall include measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," 1981 ed., which is adopted and incorporated by reference.

(c) The registrant shall maintain a record of calibrations for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(17) Periodic Quality Assurance Checks.

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to R313-30-6, which are capable of operation at greater than 50 kV.

(b) To satisfy the requirement of R313-30-6(17)(a), quality assurance checks shall meet the following requirements:

(i) The registrant shall perform quality assurance checks in accordance with written procedures established by the Radiation Therapy Physicist; and

(ii) The quality assurance check procedures shall specify the frequency at which tests or

measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in R313-30-6(16)(a). The acceptable tolerance for parameters measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in R313-30-6 (16)(a), shall be stated.

(c) The cause for a parameter exceeding a tolerance set by the Radiation Therapy Physicist shall be investigated and corrected before the system is used for patient irradiation;

(d) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiation Therapy Physicist's quality assurance check procedures, the system shall be recalibrated as required in R313-30-6(16)(a);

(e) The registrant shall use the dosimetry system described in R313-30-8(6)(b) to make the quality assurance check required in R313-30-6(17)(b);

(f) The registrant shall have the Radiation Therapy Physicist review and sign the results of radiation output quality assurance checks monthly. The interval should not exceed 30 days and shall not exceed 40 days;

(g) Therapeutic radiation machines subject to R313-30-6 shall have safety quality assurance checks of external beam radiation therapy facilities performed monthly. The interval should not exceed 30 days and shall not exceed 40 days;

(h) Notwithstanding the requirements of R313-30-6(17)(f) and R313-30-6(17)(g), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by R313-30-6(17)(f) and R313-30-6(17)(g) have been performed within the required interval immediately prior to the administration;

(i) To satisfy the requirement of R313-30-6(17)(g), safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at external beam radiation therapy room entrances;

(ii) Proper operation of the "BEAM-ON" and termination switches;

(iii) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(iv) Viewing systems;

(v) If applicable, electrically operated treatment room doors from inside and outside the treatment room;

(j) The registrant shall maintain a record of quality assurance checks required by R313-30-6(17) (a) and R313-30-6(17)(g) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

(18) Operating Procedures.

(a) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of R313-30-6(16) and R313-30-6(17) have been met;

(b) Therapeutic radiation machines shall not be left unattended unless secured pursuant to R313-30- 6(9)(e);

(c) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(d) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require holding and the peak tube potential of the system does not exceed 50 kV. In these cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, individuals, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of R313-15-201 of these rules.

R313-30-7. Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).

(1) Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(a) The absorbed dose rate due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, that is at the plane of the patient, shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(b) Except for the area defined in R313-30-7(1)(a), the absorbed dose rate, excluding that from neutrons, at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

(c) For equipment manufactured after the effective date of these rules, the neutron absorbed dose outside the useful beam shall be in compliance with applicable acceptance criteria; and

(d) For therapeutic radiation machines, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in R313-30-7(1)(a) through R313-30-7(1)(c) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by representatives of the Executive Secretary.

(2) Leakage Radiation Through Beam Limiting Devices.

(a) Photon Radiation.

(i) Adjustable or interchangeable beam limiting devices, such as the collimating jaws or x-ray cones, shall attenuate the useful beam so that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting devices shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeters by ten centimeters radiation field; and

(ii) Interchangeable beam limiting devices, such as auxiliary beam blocking material, shall attenuate the useful beam so that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the interchangeable beam limiting device shall not exceed five percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field.

(b) Electron Radiation. Adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, so that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(i) A maximum of two percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(ii) A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(c) Measurement of Leakage Radiation.

(i) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and residual apertures blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through the sets of beam limiting devices shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

(ii) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with an appropriate radiation detector suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using an appropriate amount of water equivalent build up material for the energies being measured.

(3) Filters and Wedges.

(a) Filters and wedges which are removable from the system shall be clearly marked with an identification number;

(i) For removable wedge filters, the nominal wedge angle shall appear on the wedge, or on the wedge tray if the wedge filter is permanently mounted to the tray.

(ii) If the wedge or wedge tray is damaged, the Radiation Therapy Physicist will decide if the wedge transmission factor shall be redetermined;

(b) For equipment manufactured after the effective date of these rules which utilize a system of wedge filters:

(i) Irradiation shall not be possible until a selection of a wedge filter or a positive selection to use "no wedge filter" has been made at the treatment control panel;

(ii) An interlock system shall be provided to prevent irradiation if the wedge filter selected is not in the correct position;

(iii) A display shall be provided at the treatment control panel showing the wedge filters in use; and

(iv) An interlock shall be provided to prevent irradiation if a wedge filter selection operation, either manual or automatic, carried out in the treatment room does not agree with the wedge filter selection operation carried out at the treatment control panel.

(c) If the absorbed dose rate information required by R313-30-7(8) relates exclusively to operation with a field flattening filter or beam scattering foil in place, the filter or foil shall be removable only by the use of tools. If removable, the filter or foil shall be interlocked to prevent incorrect selection and incorrect positioning.

(d) For equipment manufactured after the effective date of these rules which utilize a system of interchangeable field flattening filters or interchangeable beam scattering foils:

(i) An interlock system shall be provided to prevent irradiation if the appropriate flattening filter for the x-ray energy selected is not in the correct position in the beam;

(ii) An interlock system shall be provided to prevent irradiation if the appropriate beam scattering foil for the electron energy selected is not in the correct position in the beam;

(iii) An interlock system shall be provided to prevent irradiation if no scattering foil is in place for the electron beams, or if no flattening filter is in place for the x-ray beams; and

(iv) A display shall be provided at the treatment control panel showing a fault indicator when the interlock system has prevented irradiation. The fault indicator will identify a filter or foil error.

(4) Stray Radiation in the Useful Beam. For equipment manufactured after the effective date of these rules, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam meet applicable acceptance criteria.

(5) Beam Monitors. Therapeutic radiation machines subject to R313-30-7 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate, and to monitor other beam parameters.

(a) Equipment manufactured after the effective date of these rules shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of a common element.

(b) Equipment manufactured on or before the effective date of these rules shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

(c) The detector and the system into which that detector is incorporated shall meet the following

requirements:

(i) Detectors shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

(ii) Detectors shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(iii) The beam monitoring systems shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(iv) For equipment manufactured after the effective date of these rules, the design of the beam monitoring systems shall ensure that the:

(A) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and

(B) Failure of an element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

(v) Beam monitoring systems shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these rules, displays shall:

(A) Maintain a reading until intentionally reset;

(B) Have only one scale and no electrical or mechanical scale multiplying factors;

(C) Utilize a design so that increasing dose monitor units are displayed by increasing numbers; and

(D) In the event of power failure, the dose monitor units delivered up to the time of failure, or the beam monitoring information required in R313-30-7(5)(c)(v)(C) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

(6) Beam Symmetry.

(a) Bent-beam linear accelerators subject to R313-30-7 shall be provided with auxiliary devices to monitor beam symmetry;

(b) The devices referenced in R313-30-7(6)(a) shall be able to detect field asymmetry greater than ten percent; and

(c) The devices referenced in R313-30-7(6)(a) shall be configured to terminate irradiation if the specifications in R313-30-7(6)(b) can not be maintained.

(7) Selection and Display of Dose Monitor Units.

(a) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;

(b) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

(c) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(d) For equipment manufactured after the effective date of these rules, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

(8) Air Kerma Rate and Absorbed Dose Rate. For equipment manufactured after the effective date of these rules, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in R313-30-7 (5) may form part of this system. In addition:

(a) The dose monitor unit dose rate shall be displayed at the treatment control panel;

(b) If the equipment can deliver an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(c) If the equipment can deliver, under any fault condition, an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(d) For therapeutic radiation machines, the registrant shall determine, or obtain from the manufacturer, the maximum values specified in R313-30-7(8)(b) and R313-30-7(8)(c) for the specified operating conditions. Records of these maximum values shall be maintained at the installation for inspection by representatives of the Executive Secretary.

(9) Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

(a) Primary systems shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

(b) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(c) For equipment manufactured after the effective date of these rules, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(10) Termination Switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(11) Interruption Switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator

action without a reselection of operating conditions. If a change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(12) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

(a) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

(b) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(c) The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(13) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(a) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

(b) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(c) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

(d) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain a verification film, when electron applicators are fitted;

(e) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(f) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(14) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(b) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation; and

(c) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(15) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving

beam radiation therapy shall meet the following requirements:

(a) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(b) The mode of operation shall be displayed at the treatment control panel;

(c) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

(d) An interlock system shall be provided to prevent irradiation if a selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(e) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. For equipment manufactured after the effective date of these rules:

(i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in increments of ten degrees of rotation or one centimeter of motion differs by more than 20 percent from the selected value;

(ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units shall differ by less than five percent from the dose monitor unit value selected;

(iii) An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

(iv) For equipment manufactured after the effective date of these rules, an interlock shall be provided to require that a selection of direction be made at the treatment control panel in units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(f) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by R313-30-7(9); and

(g) For equipment manufactured after the effective date of these rules, an interlock system shall be provided to terminate irradiation if movement:

(i) Occurs during stationary beam radiation therapy; or

(ii) Does not start or stops during moving beam radiation therapy unless the stoppage is a preplanned function.

(16) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of R313-30-9, the following design requirements are made:

(a) Protective Barriers. Protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(b) Control Panel. In addition to other requirements specified in R313-30, the control panel shall also:

(i) Be located outside the treatment room;

(ii) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(iii) Provide an indication of whether radiation is being produced; and

(iv) Include an access control device which will prevent unauthorized use of the therapeutic radiation machine;

(c) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(d) Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(e) Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of access doors, which will indicate when the useful beam is "ON;"

(f) Entrance Interlocks. Interlocks shall be provided so that access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by an access control, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel;

(g) Beam Interceptor Interlocks. If the shielding material in a protective barrier requires the presence of a beam interceptor to ensure compliance with R313-30-301(1), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;

(h) Emergency Cutoff Switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by R313-30-7 (11). Emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control panel without resetting the emergency cutoff switch. Alternatively, power cannot be restarted without pressing a RESET button in the treatment room after resetting the power breaker, and the operator shall check the treatment room and patient prior to turning the power back on;

(i) Safety Interlocks. Safety interlocks shall be designed so that defects or component failures in the safety interlock system prevent or terminate operation of the therapeutic radiation machine; and

(j) Surveys for Residual Radiation. Surveys for residual activity shall be conducted on therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to

machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(17) Radiation Therapy Physicist Support.

(a) The services of a Radiation Therapy Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:

(i) Full calibrations required by R313-30-7(19) and protection surveys required by R313-30-4(1);

(ii) Supervision and review of dosimetry;

(iii) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

(iv) Quality assurance, including quality assurance check review required by R313-30-7(20)(e) of these rules;

(v) Consultation with the authorized user in treatment planning, as needed; and

(vi) Perform calculations and assessments regarding misadministrations.

(b) If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by R313-30-7(18) shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions to be taken until the Radiation Therapy Physicist can be contacted.

(18) Operating Procedures.

(a) No individual, other than the patient, shall be in the treatment room during treatment or during an irradiation for testing or calibration purposes;

(b) Therapeutic radiation machines shall not be made available for medical use unless the requirements of R313-30-4(1), R313-30-7(19) and R313-30-7(20) have been met;

(c) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(d) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(e) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(f) When adjustable beam limiting devices or beam limiting devices that do not contact the skin are used, the position and shape of the radiation field shall be indicated by a light field.

(19) Full Calibration Measurements.

(a) Full calibration of a therapeutic radiation machine subject to R313-30-7 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:

(i) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(ii) Annually. The intervals should not exceed 12 months and shall not exceed 13 months; and

(iii) Before medical use under the following conditions:

(A) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be easily reconciled; and

(B) Following component replacement, major repair, or modification of components, if the appropriate Quality Assurance checks demonstrate that the characteristics of the radiation beam have been significantly affected as determined by a Radiation Therapy Physicist. The Quality Assurance checks shall be performed by, or under the direct supervision of a Radiation Therapy Physicist. The determination of the need for a full calibration shall be made by a Radiation Therapy Physicist.

(iv) Notwithstanding the requirements of R313-30-7(19)(a)(iii):

(A) Full calibration of therapeutic radiation machines with multi-energy and multi-mode capabilities is required only for those modes and energies that are not within their range and the difference cannot be easily reconciled; and

(B) If the repair, replacement or modification does not affect all modes and energies, full calibration shall be performed on the effected mode or energy if the Quality Assurance checks demonstrate that the characteristics of the radiation beam have been significantly affected as determined by a Radiation Therapy Physicist. The Quality Assurance checks shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist. The determination of the need for a full calibration shall be made by a Radiation Therapy Physicist. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in R313-30-7(19)(a)(iii)(A).

(b) To satisfy the requirement of R313-30-7(19)(a), full calibration shall include measurements required for annual calibration by American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference;

(c) The registrant shall use the dosimetry system described in R313-30-8(6) to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in R313-30-7(19)(b) may then be made using a dosimetry system that indicates relative dose rates; and

(d) The registrant shall maintain a record of calibrations for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(20) Periodic Quality Assurance Checks.

(a) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to R313-30-7. These checks should be performed at intervals not to exceed those

intervals recommended in American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference.

(i) Determination of parameters for central axis radiation output shall be done at least weekly. The interval shall not exceed ten days.

(ii) The interval at which periodic quality assurance checks are to be performed shall be determined by the Radiation Therapy Physicist and shall be documented in the registrant's quality management program. The interval for a specific performance check may be based on the history of that performance check for a particular machine. The interval may be increased above the recommended limits only if the Radiation Therapy Physicist determines the increase is justified based on the history of the performance check for that machine or a machine of the same manufacturer and the same model.

(iii) If the performance check demonstrates a need to decrease the interval, the Radiation Therapy Physicist shall decide if the interval should be decreased. The decreased interval shall be continued until the performance check demonstrates that the decreased interval is not necessary.

(b) To satisfy the requirement of R313-30-7(20)(a), quality assurance checks shall include determination of central axis radiation output and shall include a representative sampling of periodic quality assurance checks contained in American Association of Physicists in Medicine (AAPM) Report 46, "Comprehensive Quality Assurance for Radiation Oncology," 1994 ed., which is adopted and incorporated by reference.

(i) A representative sampling shall include those referenced periodic quality assurance checks necessary to assure that the radiation beam and alignment parameters for all therapy machines and modes of operation are within limits prescribed by AAPM Report 46.

(ii) The intervals for a representative sampling of referenced periodic quality assurance checks should not exceed 12 consecutive months and shall not exceed 13 consecutive months.

(c) The registrant shall use a dosimetry system which has been inter-compared semi-annually. The intervals should not exceed six months and shall not exceed seven months, with a dosimetry system described in R313-30- 8(6)(a) to make the periodic quality assurance checks required in R313-30-7(20)(a)(i);

(d) The registrant shall perform periodic quality assurance checks required by R313-30-7(20)(a) in accordance with procedures established by the Radiation Therapy Physicist;

(e) The registrant shall review the results of periodic radiation output checks according to the following procedures:

(i) The authorized user and Radiation Therapy Physicist shall be immediately notified if a parameter is not within its acceptable range. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable range;

(ii) If periodic radiation output check parameters appear to be within their acceptable range, the periodic radiation output check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within two weeks;

(iii) The Radiation Therapy Physicist shall review and sign the results of radiation output quality

assurance checks at intervals not to exceed one month; and

(iv) Other Quality Assurance checks shall be reviewed at intervals specified in the Quality Management Program, as required by R313-30-5.

(f) Therapeutic radiation machines subject to R313-30-7 shall have safety quality assurance checks of external beam radiation therapy facilities performed weekly at intervals not to exceed ten days;

(g) To satisfy the requirement of R313-30-7(20)(f), safety quality assurance checks shall ensure proper operation of:

(i) Electrical interlocks at external beam radiation therapy room entrances;

(ii) Proper operation of the "BEAM-ON", interrupt and termination switches;

(iii) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(iv) Viewing and aural communication systems;

(v) Electrically operated treatment room doors from inside and outside the treatment room;

(vi) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, switches shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(h) The registrant shall promptly repair a system identified in R313-30-7(20)(g) that is not operating properly; and

(i) The registrant shall maintain a record of quality assurance checks required by R313-30-7(20)(a) and R313-30-7(20)(g) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

R313-30-8. Calibration and Check of Survey Instruments and Dosimetry Equipment.

(1) The registrant shall ensure that the survey instruments used to show compliance with R313-30 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(2) To satisfy the requirements of R313-30-8(1), the registrant shall:

(a) Calibrate required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(b) Calibrate at least two points on the scales to be calibrated. These points should be at approximately 1/3 and 2/3 of scale rating; and

(3) To satisfy the requirements of R313-30-8(2), the registrant shall:

(a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and

(b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(4) The registrant shall retain a record of calibrations required in R313-30-8(1) for three years. The record shall include:

(a) A description of the calibration procedure; and

(b) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(5) The registrant may obtain the services of individuals licensed by the Board, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by R313-30-8(4) shall be maintained by the registrant.

(6) Dosimetry Equipment.

(a) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated for by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within 24 months prior to use and after servicing that may have affected system calibration.

(i) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(ii) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy or energy range appropriate for the radiation being used.

(b) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with R313-30-8(6)(a). This comparison shall have been performed within the previous 12 months (six months if the dosimetry system is an ionization chamber) and after servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in R313-30-8(6)(a);

(c) The registrant shall maintain a record of dosimetry system calibration, intercomparison, and comparison for the duration of the license and registration. For calibrations, intercomparisons, or comparisons, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by R313-30-8(6)(a) and R313-30-8(6)(b), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the calibration, intercomparison, or comparison was performed by, or under the direct supervision of, a Radiation Therapy Physicist.

R313-30-9. Shielding and Safety Design Requirements.

(1) Therapeutic radiation machines subject to R313-30-6 or R313-30-7 shall be provided with the primary and secondary barriers that are necessary to ensure compliance with R313-15-201 and R313-30-301 of these rules.

(2) Facility design information for new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for approval by the Executive Secretary prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in R313-30-10.

R313-30-10. Information on Radiation Shielding Required for Plan Reviews.

(1) Therapeutic Radiation Machines

(a) Basic facility information including: name, telephone number and Department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address, including room number, of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structures.

(b) Wall, floor, and ceiling areas struck by the useful beam shall have primary barriers. For an adjacent area that is normally unoccupied, barrier thicknesses may be less than the required thickness, if:

(i) That area where the exposure rates and exposures exceed the limits specified in R313-15-301 (1) is permanently fenced or walled to prevent access;

(ii) The appropriate warning signs are posted at appropriate intervals and locations on the fence or wall;

(iii) The exposure rates and exposures outside the fence or wall are less than the limits specified in R313-15-301(1);

(iv) Access to the area is controlled by the operator, and once access is gained, the therapeutic radiation machine cannot be operated until the area has been cleared and access is again controlled by the operator;

(v) The ceiling is of sufficient thickness to reduce exposure due to skyshine, so that the exposure rates and exposures surrounding the facility are less than the limits specified in R313-15-301(1); and

(vi) The primary barrier is of sufficient thickness to ensure that the exposure rates and exposures from the primary beam in spaces in adjacent buildings are less than the limits specified in R313-15-301(1).

(c) Secondary barriers shall be provided in wall, floor, and ceiling areas not having primary barriers.

(2) Therapeutic Radiation Machines up to 150 kV (photons only). In addition to the requirements listed in R313-30-10(1), therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a

minimum, the following additional information:

(a) Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

(b) Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

(c) A facility blueprint or drawing indicating: the scale of the blueprint or drawing; direction of North; normal location of the therapeutic radiation machine's radiation ports; the port's travel and traverse limits; general directions of the useful beam; locations of windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with R313-15-101 of these rules.

(d) The structural composition and thickness or the lead or concrete equivalent of walls, doors, partitions, floor, and ceiling of the rooms concerned.

(e) The type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present.

(f) At least one example calculation which shows the methodology used to determine the amount of shielding required for the physical conditions; that is the primary and secondary or leakage barriers, restricted and unrestricted areas, entry doors; and shielding material in the facility.

(i) If commercial software is used to generate shielding requirements, please also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

(3) Therapeutic Radiation Machines over 150 kV. In addition to the requirements listed in R313-30-10(1), therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and electrons and protons or other subatomic particles shall submit shielding plans which contain, as a minimum, the following additional information:

(a) Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energies and types of radiation produced, that is photon and electron. The source to isocenter distance shall be specified.

(b) Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

(c) Facility blueprint or drawing, including both floor plan and elevation views, indicating relative orientation of the therapeutic radiation machine; scale; types; thickness and minimum density of shielding materials; direction of North; the locations and size of penetrations through shielding barriers, ceiling, walls and floor; as well as details of the doors and maze.

(d) The structural composition and thickness or concrete equivalent of walls, doors, partitions,

floor, and ceiling of the rooms concerned.

(e) The type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present.

(f) Description of assumptions that were used in shielding calculations including, but not limited to; design energy, for example a room may be designed for 6 MV unit although only a 4 MV unit is currently proposed; workload; presence of integral beam-stop in unit; occupancy and uses of adjacent areas; fraction of time that useful beam will intercept permanent barriers, walls, floor and ceiling; and "allowed" radiation exposure in both restricted and unrestricted areas.

(g) At least one example calculation which shows the methodology used to determine the amount of shielding required for the physical conditions; that is the primary and secondary or leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors and maze; and shielding material in the facility.

(i) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

(4) Neutron Shielding. In addition to the requirements listed in R313-30-10(3), therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

(a) The structural composition, thickness, minimum density and location of neutron shielding material.

(b) Description of assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron flux rate, absorbed dose and dose equivalent, due to neutrons, in both restricted and unrestricted areas.

(c) At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for the physical conditions, that is, restricted and unrestricted areas, entry doors and maze and neutron shielding material utilized in the facility.

(i) If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date.

(ii) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

(d) The methods and instrumentation which will be used to verify the adequacy of neutron shielding installed in the facility.

KEY

x-rays, survey, radiation, radiation safety

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August 13, 1999

Notice of Continuation

January 25, 1999

Authorizing, Implemented, or Interpreted Law

19-3-104

Rule R313-32. Medical Use of Radioactive Material.

As in effect on September 1, 2002

Table of Contents

R313-32-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of R313-32 are in addition to, and not in substitution for, other sections of R313.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-32-2. Definitions.

"Authorized nuclear pharmacist" means a pharmacist who is:

(a) board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;

(b) identified as an authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or

(c) identified as an authorized nuclear pharmacist on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

"Authorized user" means a physician, dentist, or podiatrist who is:

(a) board certified by at least one of the boards listed in Paragraph (1) of R313-32-910, R313-32-920, R313-32-930, R313-32-940, R313-32-950, or R313-32-960;

(b) identified as an authorized user on a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or

(c) identified as an authorized user on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.

"Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

"Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by this state.

"Dentist" means an individual licensed by this state to practice dentistry.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method, other instructions, and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Management" means the chief executive officer or that person's delegate.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgement about whether those requirements should apply in the case at hand.

"Misadministration" means the administration of:

(a) A radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I- 131:

(i) involving the wrong individual, or wrong radiopharmaceutical; or

(ii) when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administrated dosage and prescribed dosage exceeds 1.11 MBq (30 uCi).

(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

(ii) when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(c) A gamma stereotactic radiosurgery radiation dose:

(i) involving the wrong individual or wrong treatment site; or

(ii) when the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.

(d) A teletherapy radiation dose:

(i) involving the wrong individual, wrong mode of treatment, or wrong treatment site;

(ii) when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;

(iii) when the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(iv) when the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(e) A brachytherapy radiation dose:

(i) involving the wrong individual, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) involving a sealed source that is leaking;

(iii) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131, or both:

(i) involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) when the dose to the individual exceeds 0.05 Sv (five rems) effective dose equivalent or 0.5 Sv (50 rems) dose equivalent to any individual organ.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Podiatric use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of podiatry in accordance with a license issued by this State.

"Podiatrist" means an individual licensed by this State to practice podiatry.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

(a) in a written directive; or

(b) either in the diagnostic clinical procedures manual or in an appropriate record in accordance

with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

(a) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) for teletherapy, the total dose and dose per fraction as documented in the written directive; or

(c) for brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a license issued by the Executive Secretary.

"Recordable event" means the administration of:

(a) a radiopharmaceutical or radiation without a written directive where a written directive is required;

(b) a radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(c) a radiopharmaceutical dosage greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I- 131 when both:

(i) the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage, and

(ii) the difference between the administered dosage and prescribed dosage exceed 555 kBq (15 uCi);

(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;

(e) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(f) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on a license issued by the Executive Secretary.

"Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (f) of this definition, containing the following information:

(a) for any administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131: the dosage;

(b) for a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) for gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) for teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) for high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) for all other brachytherapy:

(i) prior to implantation: the radionuclide, number of sources, and source strengths; and

(ii) after implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time, or equivalently, the total dose.

R313-32-6. Provisions for Research Involving Human Subjects.

A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Utah license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

R313-32-7. FDA, other Federal, and State Requirements.

Nothing in R313-32 relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

R313-32-11. License Required.

(1) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State, or as allowed in R313-32-11(2) or (3).

(2) An individual shall receive, possess, use, or transfer radioactive material in accordance with the Utah Radiation Control Rules under the supervision of an authorized user as provided in R313-32-25, unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with R313- 32 under the supervision of an authorized nuclear pharmacist or authorized user as provided in R313-32-25, unless prohibited by license condition.

R313-32-12. Application for License, Amendment, or Renewal.

(1) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(2) An application for a license for medical use of radioactive material as described in R313-32-100, R313-32-200, R313-32-300, R313-32-400, and R313-32-500 must be made by filing of Form DRC-02, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted in a letter format.

(3) An applicant that satisfies the requirements specified in R313-22-50(2) may apply for a Type A specific license of broad scope.

R313-32-13. License Amendment.

A licensee shall apply for and receive a license amendment:

(1) before it receives or uses radioactive material for a clinical procedure permitted under R313-32 but not permitted by the license issued pursuant to R313-32;

(2) before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

(a) an authorized user certified by the organizations specified in paragraph (1) of R313-32-910, R313-32-920, R313-32-930, R313-32-940, R313-32-950, or R313-32-960;

(b) an authorized nuclear pharmacist certified by the organization specified in paragraph (1) of R313-32-980;

(c) identified as an authorized user or an authorized nuclear pharmacist on a Nuclear Regulatory Commission or an Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively, or

(d) identified as an authorized user or an authorized nuclear pharmacist on a permit issued by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

(3) before it changes Radiation Safety Officers or Teletherapy Physicists;

(4) before it orders radioactive material in excess of the amount, or radionuclide or form different than authorized on the license; and

(5) before it adds to or changes the address or addresses of use identified on the license.

R313-32-14. Notifications.

(1) A licensee shall provide to the Executive Secretary a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to R313-32-13(2)(a) through (2)(d).

(2) A licensee shall notify the Executive Secretary by letter no later than 30 days after:

(a) an authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(b) the licensee's mailing address changes.

(3) The licensee shall mail the documents required in R313-32-14 to the address identified in R313- 12-110.

R313-32-15. Exemptions Regarding Type A Specific Licenses of Broad Scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of R313-32-13(2);

(2) The provisions of R313-32-13(5) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provisions of R313-32-14(1); and

(4) The provisions of R313-32-14(2)(a) for an authorized user or an authorized nuclear pharmacist.

R313-32-18. License Issuance.

The Executive Secretary shall issue a license for the medical use of radioactive material for a term of five years provided the following requirements are met:

(1) The applicant has filed form DRC-02 "Application for Materials License - Medical" in accordance with the instructions in R313-22-32.

(2) The applicant has paid any applicable fee as provided in R313-70.

(3) The Executive Secretary finds the applicant equipped and committed to observe the safety standards established in R313-15 for the protection of the public health and safety.

(4) In addition to the requirements set forth in R313-22-33 a specific license for human use of radioactive material in institutions will be issued if:

(a) the applicant has appointed a radiation safety committee to coordinate the use of radioactive material throughout that institution and to maintain surveillance over the institution's radiation safety program; and

(b) if the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has training and experience in the use of a variety or radioactive materials for a variety of human uses, and meets the training and experience requirements of R313-32.

(5) A specific license for the human use of radioactive material will be issued to an individual physician if the following are complied with:

(a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable.

(b) The applicant has training and experience as required by R313-32, in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.

(c) The application is for use in the applicant's practice in an office outside a medical institution.

(d) The Executive Secretary shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a medical institution unless:

(i) the use of radioactive material is limited to:

(A) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(B) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(C) the performance of in vitro diagnostic studies;

(D) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(ii) the physician brings the radioactive material with him and removes the radioactive material when he departs. The institution cannot receive, possess or store radioactive material other than the amount of material remaining in the patient; or

(iii) the medical institution does not hold a radioactive material license issued pursuant to the provisions of R313-32-18(4).

R313-32-19. Specific Exemptions.

The Board may, upon application of any interested person or upon its own initiative, grant exemptions from the rules in R313-32 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Board will review requests for exemptions from training and experience requirements with the assistance of the Executive Secretary.

R313-32-20. ALARA Program.

(1) The licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(2) To satisfy the requirement of R313-32-20(1) one of the following shall be implemented:

(a) At a medical institution, management, the Radiation Safety Officer, and authorized users shall participate in the program as requested by the Radiation Safety Committee.

(b) For licensees that are not medical institutions, management and authorized users shall participate in the program as requested by the Radiation Safety Officer.

(3) The program shall include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

R313-32-21. Radiation Safety Officer.

(1) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(2) The Radiation Safety Officer shall:

(a) investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practices and implement corrective actions as necessary;

(b) establish, collect in one binder or file, and implement written policy and procedures for:

(i) authorizing the purchase of radioactive material;

(ii) receiving and opening packages of radioactive material;

(iii) storing radioactive material;

(iv) keeping an inventory record of radioactive material;

(v) using radioactive material safely;

(vi) taking emergency action if control of radioactive material is lost;

(vii) performing periodic radiation surveys;

(viii) performing checks of survey instruments and other safety equipment;

(ix) disposing of radioactive material;

(x) training personnel who work in or frequent areas where radioactive material is used or stored;

(xi) keeping a copy of all records and reports required by the Utah Radiation Control Rules, a copy of these rules, a copy of each licensing request, license and amendment, and written policy

and procedures required by the rules;

(c) brief management once a year on the radioactive material program;

(d) establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(e) establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(f) for medical use not at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management; and

(g) for medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

R313-32-22. Radiation Safety Committee.

The medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

(1) The Committee shall meet the following administrative requirements:

(a) Membership shall consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(b) The Committee shall meet at least quarterly.

(c) To establish a quorum and to conduct business, at least one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.

(d) The minutes of each Radiation Safety Committee meeting shall include:

(i) the date of the meeting;

(ii) members present;

(iii) members absent;

(iv) summary of deliberations and discussions;

(v) recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in R313-32-20.

(e) The Committee shall promptly provide the members with copies of the meeting minutes, and retain one copy for the duration of the license.

(2) To oversee the use of licensed material, the Committee shall:

(a) review recommendations on ways to maintain individual and collective doses ALARA;

(b)(i) review, on the basis of safety and with regard to the training and experience standards in R313-32-900 through R313-32-981, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal; or

(ii) review, pursuant to R313-32-13(2)(a) through (2)(d), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(c) review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under R313-32-31;

(d) review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of personnel working with radioactive material;

(e) review quarterly, with the assistance of the Radiation Safety Officer, incidents involving radioactive material with respect to cause and subsequent actions taken; and

(f) review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

R313-32-23. Statements of Authority and Responsibilities.

(1) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(a) identify radiation safety problems;

(b) initiate, recommend, or provide corrective actions; and

(c) verify implementation of corrective actions.

(2) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Executive Secretary terminates the license.

R313-32-25. Supervision.

(1) A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by R313-32-11(2) shall:

(a) instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

(b) require the supervised individual to follow the instructions of the supervising authorized user,

follow the written radiation safety and quality management procedures established by the licensee, and comply with the Utah Radiation Control Rules and the license conditions with respect to the use of radioactive material; and

(c) periodically review the supervised individual's use of radioactive material and the records kept to reflect this use.

(2) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by R313-32- 11(3), shall:

(a) instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of radioactive material;

(b) require the supervised individual to follow the instructions given pursuant to R313-32-25(2)(a) and to comply with these rules and license conditions; and

(c) require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

(3) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

R313-32-29. Administrative Requirements that Apply to the Providers of Mobile Nuclear Medicine Service.

(1) The Executive Secretary will license mobile nuclear medicine service only in accordance with R313-32-100, R313-32-200, and R313-32-500.

(2) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(3) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the rules while the mobile nuclear medicine service is under the client's direction.

(4) A mobile nuclear medicine service shall not order radioactive material to be delivered directly from the manufacturer or distributor to the client's address of use.

R313-32-31. Radiation Safety Program Changes.

(1) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in R313-32-13 and R313-32-606. A licensee is responsible for assuring that any change made is in compliance with the requirements of the rules and the license.

(2) A licensee shall retain a record of each change until the license has been renewed or terminated. The record shall include the effective date of the change, a copy of the old and new

radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

R313-32-32. Quality Management Program.

(1) The applicant or licensee shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(a) that, prior to administration, a written directive is prepared for:

(i) teletherapy radiation doses;

(ii) gamma stereotactic radiosurgery radiation doses;

(iii) brachytherapy radiation doses;

(iv) administration of quantities greater than 1.11 MBq (30 uCi) of either sodium iodide I-125 or I-131;

(v) therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(b) that the following are exceptions to the written directive:

(i) if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision;

(ii) also, a written revision to an existing written directive may be made for a diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose; or

(iii) if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive;

(c) that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(d) that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(e) that each administration is in accordance with the written directive; and

(f) that each unintended deviation from the written directive is identified and evaluated, and

appropriate action is taken.

(2) The licensee shall:

(a) develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) a representative sample of patient and human research subject administrations,

(ii) all recordable events, and

(iii) all misadministrations to verify compliance with each aspect of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(b) evaluate these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of R313-32-32(1); and

(c) retain records of the review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(a) assembling the relevant facts including the cause;

(b) identifying what, if applicable, corrective action is required to prevent recurrence; and

(c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if applicable, was taken.

(4) The licensee shall retain:

(a) a written directive; and

(b) a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in R313-32-32(1)(a), in an auditable form, for three years after the date of administration.

(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Executive Secretary within 30 days after the modification has been made.

(6)(a) Applicants for a new license, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Executive Secretary.

(b) Existing licensees, as applicable, shall submit to the Executive Secretary in accordance with R313-12-110, prior to March 1, 1995, a written certification that the quality management program has been implemented along with a copy of the program.

R313-32-33. Notifications, Reports and Records of Misadministrations.

(1) For a misadministration:

(a) the licensee shall notify the Executive Secretary by telephone no later than the next calendar day after discovery of the misadministration.

(b) the licensee shall submit a written report to the Executive Secretary within 15 days after discovery of the misadministration. The written report shall include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and if there was notification, what information was provided. The report must not include the individual's name or any other information that could lead to identification of the individual. To meet the requirements of R313-32-33, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(c) the licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(d) if the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) a copy of the report that was submitted to the Executive Secretary; or

(ii) a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the Executive Secretary can be obtained from the licensee.

(2) The licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(3) Aside from the notification requirement, nothing in R313-32-33 affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relative or guardian.

R313-32-49. Suppliers for Sealed Sources or Devices for Medical Use.

A licensee may use for medical use only:

(1) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the rules in R313-22 and R313-22-75(10) or the equivalent

requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to R313-22 or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State.

R313-32-50. Possession, Use, Calibration, and Check of Dose Calibrators.

(1) A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon- emitting radionuclides prior to administration to each patient or human research subject.

(2) A licensee shall:

(a) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy this requirement, the check shall be done on a frequently used setting with a sealed source of not less than 370 kBq (ten uCi) of radium-226 or 1.85 MBq (50 uCi) for a photon-emitting radionuclide;

(b) test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within five percent of its stated activity, whose activity is at least 370 kBq (ten uCi) for radium-226 and 1.85 MBq (50 uCi) for a photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(c) test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 MBq (30 uCi); and

(d) test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(3) A licensee shall also perform appropriate checks and tests required by R313-32-50 following adjustment or repair of the dose calibrator.

(4) A licensee shall mathematically correct dosage readings for geometry or linearity errors that exceed ten percent if the dosage is greater than 370 kBq (ten uCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent.

(5) A licensee shall retain a record of each check and test required by R313-32-50 for three years unless directed otherwise. The records required in R313-32-50(2)(a) through (2)(d) shall include:

(a) for R313-32-50(2)(a), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(b) for R313-32-50(2)(b), the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test;

(c) for R313-32-50(2)(c), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual

performing the test; and

(d) for R313-32-50(2)(d), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

R313-32-51. Calibration and Check of Survey Instruments.

(1) A licensee shall calibrate the survey instruments used to show compliance with R313-32 before first use, annually, and following repair. The licensee shall:

(a) calibrate all scales with readings up to ten mSv (1000 mrem) per hour with a radiation source;

(b) calibrate two separated readings on each scale that shall be calibrated. The readings shall be separated by 50 percent of the scale reading; and

(c) conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(2) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(3) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(4) A licensee shall retain a record of each survey instrument calibration for three years. The record shall include:

(a) a description of the calibration procedure; and

(b) the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

R313-32-52. Possession, Use, Calibration, and Check of Instruments to Measure Dosages or Alpha- or Beta-emitting Radionuclides.

(1) R313-32-52 does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State.

(2) For other than unit dosages obtained pursuant to R313-32-52(1), a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and

make adjustments when necessary; and

(b) check each instrument for constancy and proper operation at the beginning of each day of use.

R313-32-53. Measurement of Dosages of Unsealed Radioactive Material for Medical Use.

A licensee shall:

(1) measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;

(2) measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; and

(3) retain a record of the measurements required by R313-32-53 for three years. To satisfy this requirement, the record shall contain the following:

(a) generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(b) patient's or human research subject's name, and identification number if one has been assigned;

(c) prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 MBq (30 uCi);

(d) date and time of the measurement; and

(e) initials of the individual who made the record.

R313-32-57. Authorization for Calibration and Reference Sources.

Persons authorized by R313-32-11 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(1) sealed sources manufactured and distributed by a person licensed pursuant to R313-22-75 (10) or equivalent Nuclear Regulatory Commission or Agreement State regulations and that do not exceed 555 MBq (15 mCi) each;

(2) radioactive material listed in R313-32-100 or R313-32-200 with a half-life not longer than 100 days in individual amounts not to exceed 555 MBq (15 mCi);

(3) radioactive material listed in R313-32-100 or R313-32-200 with a half-life longer than 100 days in individual amounts not to exceed 7.4 MBq (200 uCi); and

(4) technetium-99m in individual amounts not to exceed 1.85 GBq (50 mCi).

R313-32-59. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) A licensee in possession of sealed sources or brachytherapy sources shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(2) A licensee in possession of a sealed source shall:

(a) test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(b) test the source for leakage at intervals not to exceed six months or at other intervals approved by the Executive Secretary, the Nuclear Regulatory Commission or an Agreement State and described in the label or brochure that accompanies the source.

(3) To satisfy the leak test requirements of R313-32-59, the licensee must:

(a) take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(b) take teletherapy and other device source test samples when the source is in the "off" position; and

(c) measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 uCi) of radioactive material on the sample.

(4) A licensee shall retain leakage test records for five years. The records shall contain the model number, the serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels or microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(5) If the leakage test reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination, the licensee shall:

(a) immediately withdraw the sealed source from use and store it in accordance with the requirements in R313-15; and

(b) file a report within five days of the leakage test with the Executive Secretary describing the equipment involved, the test results, and the action taken.

(6) A licensee need not perform a leakage test on the following sources:

(a) sources containing only radioactive material with a half-life of less than 30 days;

(b) sources containing only radioactive material as a gas;

(c) sources containing 3.7 MBq (100 uCi) or less of beta or gamma-emitting material or 370 kBq (ten uCi) or less of alpha-emitting material;

(d) sources stored and not being used. The licensee shall, however, test each source for leakage

before use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(e) seeds of iridium-192 encased in nylon ribbon.

(7) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all sources in its possession. The licensee shall retain inventory records for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(8) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(9) A licensee shall retain a record of each survey required in R313-32-59(8) for three years. The record shall include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

R313-32-60. Syringe Shields and Labels.

(1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(2) To identify its contents, a licensee shall conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label shall show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name.

(3) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient or human research subject.

R313-32-61. Vial Shields and Labels.

(1) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(2) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label shall show the radiopharmaceutical name or its abbreviation.

R313-32-70. Surveys for Contamination and Ambient Radiation Exposure Rate.

(1) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(3) A licensee shall conduct the surveys required by R313-32-70(1) and (2) so as to be able to

detect dose rates as low as one uSv (0.1 mrem) per hour.

(4) A licensee shall establish radiation dose rate trigger levels for the surveys required by R313-32-70(1) and (2). A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(5) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(6) A licensee shall conduct the survey required by R313-32-70(5) so as to be able to detect contamination on each wipe sample of 2200 disintegrations per minute, (0.001 uCi or 37 Bq).

(7) A licensee shall establish removable contamination trigger levels for the surveys required by R313-32-70(5). A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(8) A licensee shall retain a record of each survey for three years. The record shall include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in microsieverts or millirem per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels or curies) per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

R313-32-75. Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

(1) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

NOTE: The Nuclear Regulatory Commission Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(2) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

(a) guidance on the interruption or discontinuation of breast-feeding, and

(b) information on the consequences of failure to follow the guidance.

(3) The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(a) using the retained activity rather than the activity administered,

(b) using an occupancy factor less than 0.25 at 1 meter,

(c) using the biological or effective half-life, or

(d) considering the shielding by tissue.

(4) The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast- feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

R313-32-80. Technical Requirements that Apply to the Providers of Mobile Nuclear Medicine Service.

A licensee providing mobile nuclear medicine service shall:

(1) transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(2) bring into each address of use all radioactive material to be used and, before leaving, remove all unused radioactive material and all associated waste;

(3) secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

(4) check survey instruments and dose calibrators as described in R313-32-50 and R313-32-51 and check all other transported equipment for proper function before medical use at each address of use;

(5) carry a radiation detection survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed; and

(6) retain a record of each survey required in R313-32-80(5) for three years. The record shall include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts or millirems per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

R313-32-90. Storage of Volatiles and Gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

R313-32-92. Decay-In-Storage.

(1) A licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of R313-15-1001 if it:

(a) holds radioactive material for decay a minimum of ten half-lives;

(b) monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed

shielding;

(c) removes or obliterates all radiation labels; and

(d) separates and monitors each generator column individually with radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(2) A licensee shall retain a record of each disposal permitted under R313-32-92(1) for three years. The record shall include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

R313-32-100. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that is either:

(1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-120. Possession of Survey Instrument.

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour.

R313-32-200. Use of Unsealed Radioactive Material for Imaging and Localization Studies.

A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

(1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-204. Permissible Molybdenum-99 Concentration.

(1) A licensee shall not administer to humans a radiopharmaceutical containing more than 5.55 kBq (0.15 uCi) of molybdenum-99 per 37.0 MBq (one mCi) of technetium-99m.

(2) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each elute or

extract.

(3) A licensee that is required to measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in megabecquerels or millicuries, the measured activity of the molybdenum expressed in kilobecquerels or microcuries, the ratio of the measures expressed as kilobecquerels or microcuries of molybdenum per megabecquerels or millicuries of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

R313-32-205. Control of Aerosols and Gases.

(1) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed in R313-15-201(4) and R313-15-301. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(2) A licensee shall administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(3) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit as specified in R313-15-201. The calculation shall be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(4) A licensee shall make a record of the calculations required in R313-32-205(3) that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(5) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months. Records of the measurement shall be kept for three years.

R313-32-220. Possession of Survey Instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-300. Use of Unsealed Radioactive Material for Therapeutic Administration.

A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

(1) obtained from a manufacturer or preparer licensed pursuant to R313-22-75(9) or equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

(2) prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R313-32-920, or an individual under the supervision of either as specified in R313-32-25.

R313-32-310. Safety Instruction.

(1) A licensee shall provide radiation safety instruction for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with R313-32-75. To satisfy this requirement, the instruction shall describe the licensee's procedures for:

(a) patient or human research subject control;

(b) visitor control;

(c) contamination control;

(d) waste control; and

(e) notification of the Radiation Safety Officer in case of the patient's or the human research subjects's death or medical emergency.

(2) A licensee shall keep for three years a list of individuals receiving instruction required by R313-32-310(1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-315. Safety Precautions.

(1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with R313-32-75, a licensee shall:

(a) provide a private room with a private sanitary facility;

(b) post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or the human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

(c) authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313- 15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(e) either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste;

(f) survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(g) measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by R313-15-1107 a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(2) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

R313-32-320. Possession of Survey Instruments.

A licensee authorized to use radioactive material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-400. Use of Sources for Brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(2) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(3) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(4) Iridium-192 as seeds encased in nylon ribbon for interstitial and intracavitary treatment of cancer and as seeds for topical treatment of cancer;

(5) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions;

(6) Iodine-125 as a sealed source in seeds for topical, interstitial and intracavitary treatment of cancer;

(7) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

R313-32-404. Release of Patients or Human Research Subjects Treated With Temporary Implants.

(1) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(2) A licensee shall retain a record of patient or human research subject surveys for three years. Each record shall include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as microsieverts per hour or millirem per hour and measured at one meter from the patient or the human research

subject, the survey instrument used, and the initials of the individual who made the survey.

R313-32-406. Brachytherapy Sources Inventory.

(1) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(2) A licensee shall make a record of brachytherapy source use which shall include:

(a) the names of the individuals permitted to handle the sources;

(b) the number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(c) the number and activity of sources returned to storage, the patient's or the human research subject's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(3) Immediately after implanting sources in a patient or a human research subject the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(4) A licensee shall retain the records required in R313-32-406(2) and (3) for three years.

R313-32-410. Safety Instruction.

(1) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant therapy. To satisfy this requirement, the instruction shall describe:

(a) size and appearance of the brachytherapy sources;

(b) safe handling and shielding instructions in case of a dislodged source;

(c) procedures for patient or human research subject control;

(d) procedures for visitor control; and

(e) procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

(2) A licensee shall retain for three years a record of individuals receiving instruction required by R313-32-410(1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-415. Safety Precautions.

(1) For each patient or human research subject receiving implant therapy and not released from

licensee control pursuant to R313-32-75, a licensee shall:

(a) not quarter the patient or the human research subject in the same room with an individual who is not receiving radiation therapy;

(b) post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(c) authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of R313- 15, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts or millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(e) provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the individual if the individual was administered a permanent implant.

(2) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

R313-32-420. Possession of Survey Instrument.

A licensee authorized to use radioactive material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-500. Use of Sealed Sources for Diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(1) iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(2) iodine-125 as a sealed source in a portable imaging device.

R313-32-520. Availability of Survey Instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv per hour to (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour. The instrument shall be calibrated in accordance with R313-32-51.

R313-32-600. Use of a Sealed Source in a Teletherapy Unit.

The rules and provisions of R313-32-600 through R313-32-647 govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

R313-32-605. Maintenance and Repair Restrictions.

Only a person specifically licensed by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall:

(1) install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(2) maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

R313-32-606. License Amendments.

In addition to the changes specified in R313-32-13, a licensee shall apply for and shall receive a license amendment before:

(1) making any change in the treatment room shielding;

(2) making any change in the location of the teletherapy unit within the treatment room;

(3) using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(4) relocating the teletherapy unit; or

(5) allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

R313-32-610. Safety Instruction.

(1) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions shall inform the operator of:

(a) the procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption; and

(b) the procedure to be followed if:

(i) the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) the names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(2) A licensee shall provide instruction in the topics identified in R313-32-610(1) to individuals

who operate a teletherapy unit.

(3) A licensee shall retain for three years a record of individuals receiving instruction required by R313-32-610(2), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

R313-32-615. Safety Precautions.

(1) A licensee shall control access to the teletherapy room by a door at each entrance.

(2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(a) prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(b) turn the primary beam of radiation off immediately when an entrance door is opened; and

(c) prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(3) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(4) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(a) A radiation monitor shall provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and shall be observable by an individual entering the teletherapy room.

(b) A radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(c) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(d) A licensee shall maintain a record of the check required by R313-32-615(4)(c) for three years. The record shall include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(e) If a radiation monitor is inoperable, the licensee shall require individuals entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in R313-32-615(4)(d).

(f) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(5) A licensee shall construct or equip each teletherapy room to permit continuous observation of

the patient or the human research subject from the teletherapy unit console during irradiation.

R313-32-620. Possession of Survey Instrument.

A licensee authorized to use radioactive material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to one mSv (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (one mrem) per hour to ten mSv (1000 mrem) per hour.

R313-32-630. Dosimetry Equipment.

(1) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(a) The system shall be calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(b) The system shall have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting shall have indicated that the calibration factor of the licensee's system had not changed by more than two percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with R313-32- 630(1). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in R313-32-630(1).

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by R313-32-630(1) and (2), the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

R313-32-632. Full Calibration Measurements.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) before the first medical use of the unit; and

(b) before medical use under the following conditions:

(i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the source or following reinstallation of the teletherapy unit in a new location; or

(iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) at intervals not exceeding one year.

(2) To satisfy the requirement of R313-32-632(1), full calibration measurements shall include determination of:

(a) the output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) the uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) timer constancy and linearity over the range of use;

(e) on-off error; and

(f) the accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in R313-32-630(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in R313-32-632(2)(a) may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by R313-32-632(1) in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-711, and Vol. 11, No. 2, 1984, p. 213.

(5) A licensee shall correct mathematically the outputs determined in R313-32-632(2)(a) for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(6) Full calibration measurement required in R313-32-632(1) and physical decay corrections required by R313-32-632(5) shall be performed by the licensee teletherapy physicist.

(7) A licensee shall retain a record of each calibration for the duration of the teletherapy unit source. The record shall include the date of the calibration, the manufacturer's name, model

number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

R313-32-634. Periodic Spot-Checks.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(a) timer constancy, and timer linearity over the range of use;

(b) on-off error;

(c) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) the accuracy of all distance measuring and localization devices used for medical use;

(e) the output for one typical set of operating conditions measured with the dosimetry system described in R313-32-630(2); and

(f) the difference between the measurement made in R313-32-634(2)(e) and the anticipated output, expressed as a percentage of the anticipated output (the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by R313-32-634(1) in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks for each teletherapy facility once in each calendar month that assure proper operation of:

(a) electrical interlocks at each teletherapy room entrance;

(b) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(c) beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) viewing systems;

(e) treatment room doors from inside and outside the treatment room; and

(f) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) A licensee shall arrange for prompt repair of any system identified in R313-32-634(4) that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(6) A licensee shall retain a record of each spot-check required by R313-32-634(1) and (4) for three years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

R313-32-636. Safety Checks for Teletherapy Facilities.

(1) A licensee shall promptly check all systems listed in R313-32-634(4) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by R313-32-606(1) through (4).

(2) If the results of the checks required in R313-32-636(1) indicate the malfunction of a system specified in R313-32-634(4), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(3) A licensee shall retain for three years a record of the facility checks following installation of a source. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

R313-32-641. Radiation Surveys for Teletherapy Facilities.

(1) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by R313-32-606(1) through (4), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with R313-32-51 to verify that:

(a) the maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 uSv (ten mrem) per hour and 20 uSv (two mrem) per hour, respectively;

(b) with the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of the radiation, that:

(i) radiation dose rates in restricted areas are not likely to cause any occupationally exposed individual to receive a dose in excess of the limits specified in R313-15-201; and

(ii) radiation dose rates in controlled or unrestricted areas are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in R313-15-301.

(2) If the results of the surveys required in R313-32-641(1) indicate any radiation dose quantity per unit time in excess of the respective limit specified in R313-32-641(1), the licensee shall lock the control in the off position and not use the unit:

(a) except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(b) until the licensee has received a specific exemption pursuant to R313-12-54.

(3) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microseverts or millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

R313-32-643. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

(1) If the survey required by R313-32-641 indicates that an individual member of the public is likely to receive a dose in excess of the limits specified in R313-15-301, the licensee shall, before beginning the treatment program:

(a) either equip the unit with stops or add additional radiation shielding to ensure compliance with R313-15-301(3);

(b) perform the survey required by R313-32-641 again; and

(c) include in the report required by R313-32-645 the results of the initial survey, a description of the modification made to comply with R313-32-643(1)(a), and the results of the second survey.

(2) As an alternative to the requirements set out in R313-32-643(1), a licensee may request a license amendment under R313-15-301(3) that authorizes radiation levels in unrestricted areas greater than those permitted by R313- 15-301(1). A licensee shall not begin the treatment program until the license amendment has been issued.

R313-32-645. Reports of Teletherapy Surveys, Checks, Tests and Measurements.

A licensee shall mail a copy of the records required in R313-32-636, R313-32-641, R313-32-643, and the output from the teletherapy source expressed as coulombs/kilogram (roentgens) or gray (rad) per hour at one meter from the source and determined during the full calibration required in R313-32-632 to the Executive Secretary within thirty days following completion of the action that initiated the record requirement.

R313-32-647. Five-Year Inspection.

(1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Executive Secretary, the Nuclear Regulatory Commission, or an Agreement State.

(3) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

R313-32-900. Radiation Safety Officer.

Except as provided in R313-32-901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in R313-32-21 to be an individual who:

(1) is certified by:

(a) American Board of Health Physics in comprehensive health physics;

(b) American Board of Radiology;

(c) American Board of Nuclear Medicine;

(d) American Board of Science in nuclear medicine;

(e) Board of Pharmaceutical Specialties in nuclear pharmacy;

(f) American Board of Medical Physics in radiation oncology physics;

(g) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(h) American Osteopathic Board of Radiology; or

(i) American Osteopathic Board of Nuclear Medicine; or

(2) has had classroom and laboratory training and experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiation biology; and

(v) radiopharmaceutical chemistry; and

(b) one year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material; or

(3) be an authorized user identified on the licensee's license.

R313-32-901. Training for Experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a license issued by the Executive Secretary, Nuclear Regulatory Commission or Agreement State before January 1, 1989, need not comply with the training requirements of R313-32-900.

R313-32-910. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in R313-32-970 and R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical in R313-32-100(1) to be a physician who:

(1) is certified in:

(a) nuclear medicine by the American Board of Nuclear Medicine;

(b) diagnostic radiology by the American Board of Radiology;

(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(a) 40 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiation biology; and

(v) radiopharmaceutical chemistry; and

(b) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) collaborating with the authorized user in the interpretation of radionuclide test results; and

(v) patient or human research subject follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in the topics identified in R313-32-910(2).

R313-32-920. Training for Imaging and Localization Studies.

Except as provided in R313-32-970 or R313-32-971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in R313-32-200(1) to be a physician who:

(1) is certified in:

(a) nuclear medicine by the American Board of Nuclear Medicine;

(b) diagnostic radiology by the American Board of Radiology;

(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(e) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) radiopharmaceutical chemistry; and

(v) radiation biology; and

(b) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) calculating and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent the misadministration of radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) eluting technetium-99m from generator systems, measuring and testing the elute for molybdenum-99 and alumina contamination, and processing the elute with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(c) 500 hours of supervised clinical experience under the supervision of the authorized user that includes:

(i) examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) patient or human research subject follow-up; or

(3) has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in the topics identified in R313-32-920(2).

R313-32-930. Training for Therapeutic Use of Unsealed Radioactive Material.

Except as provided in R313-32-970, the licensee shall require the authorized user of radiopharmaceuticals in R313-32-300 to be a physician who:

(1) is certified by:

(a) the American Board of Nuclear Medicine;

(b) the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(c) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(d) the American Osteopathic Board of Radiology after 1984; or

(2) has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology; and

(b) supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals; and

(ii) use of iodine-131 for treatment of thyroid carcinoma in three individuals.

R313-32-932. Training for Treatment of Hyperthyroidism.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity; and

(d) radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in ten individuals.

R313-32-934. Training for Treatment of Thyroid Carcinoma.

Except as provided in R313-32-970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity; and

(d) radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three individuals.

R313-32-940. Training for Use of Brachytherapy Sources.

Except as provided in R313-32-970 the licensee shall require the authorized user of a brachytherapy source listed in R313-32-400 for therapy to be a physician who:

(1) is certified in:

(a) radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) radiation oncology by the American Osteopathic Board of Radiology;

(c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology;

(b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) checking survey meters for proper operation;

(iii) preparing, implanting, and removing sealed sources;

(iv) maintaining running inventories of material on hand;

(v) using administrative controls to prevent the misadministration of radioactive material; and

(vi) using emergency procedures to control radioactive material; and

(c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) selecting the proper brachytherapy sources and dose and method of administration;

(iii) calculating the dose; and

(iv) post-administration follow-up and review of case histories in collaboration with the authorized user.

R313-32-941. Training for Ophthalmic Use of Strontium-90.

Except as provided in R313-32-970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(1) 24 hours of classroom and laboratory training that includes:

(a) radiation physics and instrumentation;

(b) radiation protection;

(c) mathematics pertaining to the use and measurement of radioactivity; and

(d) radiation biology.

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(a) examination of each individual to be treated;

(b) calculation of the dose to be administered;

(c) administration of the dose; and

(d) follow-up and review of each individual's case history.

R313-32-950. Training for Use of Sealed Sources for Diagnosis.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source in a device listed in R313-32-500 to be a physician, dentist, or podiatrist who:

(1) is certified in

(a) radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) nuclear medicine by the American Board of Nuclear Medicine;

(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) has had eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

(a) radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(b) radiation biology;

(c) radiation protection; and

(d) training in the use of the device for the uses requested.

R313-32-960. Training for Teletherapy.

Except as provided in R313-32-970, the licensee shall require the authorized user of a sealed source listed in R313-32-600 in a teletherapy unit to be a physician who:

(1) is certified in:

(a) radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) radiation oncology by the American Osteopathic Board of Radiology;

(c) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

(a) 200 hours of classroom and laboratory training that includes:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology;

(b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) review of the full calibration measurements and periodic spot checks;

(ii) preparing treatment plans and calculating treatment times;

(iii) using administrative controls to prevent misadministrations;

(iv) implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) checking and using survey meters; and

(c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(ii) selecting the proper dose and how it is to be administered;

(iii) calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

(iv) post-administration follow-up and review of case histories.

R313-32-961. Training for Teletherapy Physicist.

The licensee shall require the teletherapy physicist to be an individual who:

(1) is certified by the American Board of Radiology in:

(a) therapeutic radiological physics;

(b) roentgen ray and gamma ray physics;

(c) x-ray and radium physics; or

(d) radiological physics; or

(2) is certified by the American Board of Medical Physics in radiation oncology physics; or

(3) holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in R313-32-59, R313-32-632, R313-32-634 and R313-32-641.

R313-32-970. Training for Experienced Authorized Users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a license issued by the Executive Secretary, Nuclear Regulatory Commission, or Agreement State license issued before January 1, 1989, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of R313-32-900 to R313-32-961.

R313-32-971. Physician Training in a Three Month Program.

A physician who, before October 1, 1988, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of R313-32-910 or R313-32-920.

R313-32-972. Recentness of Training.

The training and experience specified in R313-32-900 through R313-32-981 shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R313-32-980. Training for an Authorized Nuclear Pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(2)(a) has completed 700 hours in a structured educational program consisting of both:

(i) didactic training in the following areas:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity;

(D) chemistry of radioactive material for medical use; and

(E) radiation biology; and

(ii) supervised experience in a nuclear pharmacy involving the following:

(A) shipping, receiving, and performing related radiation surveys;

(B) using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) using administrative controls to avoid mistakes in the administration of radioactive material;

(E) using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(b) has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

R313-32-981. Training for Experienced Nuclear Pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in R313-32-980(2)(a) before January 1, 1998 and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (See R313-32-980(2)(b)) and recentness of training (See R313-32-972) to qualify as an authorized nuclear pharmacist.

R313-32-999. Resolution of Conflicting Requirements During Transition Period.

If the rules in R313-32 conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Bureau of Radiation Control, Department of Health, before January 1, 1989, and has not been renewed since January 1, 1989, then the requirements in the license will apply. However, if the licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under R313-32-31, the portion changed shall comply with the requirements of R313-32. At the time of license renewal and thereafter, these amendments to R313-32 shall apply.

KEY

radioactive material, radiopharmaceutical, brachytherapy, nuclear medicine

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September 14, 2001

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19-3-104; 19-3-108

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Rule R313-34. Requirements for Irradiators.

As in effect on September 1, 2002

Table of Contents

R313-34-1. Purpose and Authority.

(1) Rule R313-34 prescribes requirements for the issuance of licenses authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(3) and 19-3-104(6).

(3) The requirements of Rule R313-34 are in addition to, and not in substitution for, the other requirements of these rules.

R313-34-2. Scope.

(1) Rule R313-34 shall apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources; underwater irradiators in which both the source and the product being irradiated are under water; and irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type.

(2) The requirements of Rule R313-34 shall not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel, medical radiology or teletherapy, the irradiation of materials for nondestructive testing purposes, gauging, or open-field agricultural irradiations.

R313-34-3. Clarifications or Exemptions.

For purposes of Rule R313-34, 10 CFR 36, 2001 ed., is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: 36.1, 36.5, 36.8, 36.11, 36.17, 36.19(a), 36.91, and 36.93;

(2) The substitution of the following:

(a) Radiation Control Act for Atomic Energy Act of 1954;

(b) Utah Radiation Control Rules for the reference to NRC regulations and the Commission's regulations;

(c) The Executive Secretary or the Executive Secretary's for the Commission or the Commission's, and NRC in the following 10 CFR sections: 36.13, 36.13(f), 36.15, 36.19(b), 36.53(c), 36.69, and 36.81(a), 36.81(d) and 36.81(e); and

(d) In 10 CFR 36.51(a)(1), Rule R313-15 for NRC;

(3) Appendix B of 10 CFR Part 20 refers to the 2001 ed. of 10 CFR; and

(4) The substitution of Title R313 references for the following 10 CFR references:

(a) Section R313-12-51 for reference to 10 CFR 30.51;

(b) Rule R313-15 for the reference to 10 CFR 20;

(c) Subsection R313-15-501(3) for the reference to 10 CFR 20.1501(c);

(d) Section R313-15-902 for the reference to 10 CFR 20.1902;

(e) Rule R313-18 for the reference to 10 CFR 19;

(f) Section R313-19-41 for the reference to 10 CFR 30.41;

(g) Section R313-19-50 for the reference to 10 CFR 30.50;

(h) Section R313-22-33 for the reference to 10 CFR 30.33;

(i) Section R313-22-210 for the reference to 10 CFR 32.210;

(j) Section R313-22-35 for the reference to 10 CFR 30.35; and

(k) Rule R313-70 for the reference to 10 CFR 170.31.

KEY

irradiator, survey, radiation, radiation safety

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Rule converted into HTML by the Division of Administrative Rules.

For questions regarding the *content* or *application* of rules under Title R313, please contact the promulgating agency (Environmental Quality, Radiation Control). A list of agencies with links to their homepages is available at **http://www.utah.gov/government/agencylist.html.**

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Rule R313-35. Requirements for X-Ray Equipment Used for Non-Medical Applications.

As in effect on September 1, 2002

Table of Contents

R313-35-1. Purpose and Scope.

(1) R313-35 establishes radiation safety requirements for registrants who use electronic sources of radiation for industrial radiographic applications, analytical applications or other non-medical applications. Registrants engaged in the production of radioactive material are also subject to the requirements of R313-19 and R313-22. The requirements of R313-35 are an addition to, and not a substitution for, the requirements of R313-15, R313-16, R313-18 and R313-70.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

R313-35-2. Definitions.

As used in R313-35:

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials by either x-ray fluorescence or diffraction analysis.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure, hereinafter termed "cabinet," which, independent of existing architectural structure except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals, and similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

"Collimator" means a device used to limit the size, shape and direction of the primary radiation beam.

"Direct reading dosimeter" means an ion-chamber pocket dosimeter or an electronic personal dosimeter.

"External surface" means the outside surfaces of cabinet x-ray systems, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across an aperture or port.

"Fail-safe characteristics" means design features which cause beam port shutters to close, or otherwise prevent emergence of the primary beam, upon the failure of a safety or warning device.

"Nondestructive testing" means the examination of the macroscopic structure of materials by nondestructive methods utilizing x-ray sources of radiation.

"Non-medical applications" means uses of x-ray systems except those used for providing diagnostic information or therapy on human patients.

"Normal operating procedures" means instructions necessary to accomplish the x-ray procedure being performed. These procedures shall include positioning of the equipment and the object being examined, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

"Open-beam configuration" means a mode of operation of an analytical x-ray system in which individuals could accidentally place some part of the body into the primary beam during normal operation if no further safety devices are incorporated.

"Portable package inspection system" means a portable x-ray system designed and used for determining the presence of explosives in a package.

"Primary beam" means ionizing radiation which passes through an aperture of the source housing via a direct path from the x-ray tube located in the radiation source housing.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could

result in individuals receiving an absorbed dose in excess of five Gy (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes, minimally, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

R313-35-20. Personnel Monitoring.

Registrants using x-ray systems in non-medical applications shall meet the requirements of R313-15- 502.

R313-35-30. Locking of X-ray Systems Other Than Veterinary X-Ray Systems.

The control panel of x-ray systems located in uncontrolled areas shall be equipped with a locking device that will prevent the unauthorized use of a x-ray system or the accidental production of radiation. Non-cabinet x- ray systems shall be kept locked with the key removed when not in use.

R313-35-40. Storage Precautions.

X-ray systems shall be secured to prevent tampering or removal by unauthorized personnel.

R313-35-50. Training Requirements.

In addition to the requirements of R313-18-12, an individual operating x-ray systems for non-medical applications shall be trained in the operating procedures for the x-ray system and the emergency procedures related to radiation safety for the facility. Records of training shall be made and maintained for three years after the termination date of the individual.

R313-35-60. Surveys.

In addition to the requirements of R313-15-501, radiation surveys of x-ray systems shall be performed:

(1) upon installation of the x-ray system; and

(2) following change to or maintenance of components of an x-ray system which effect the output, collimation, or shielding effectiveness.

R313-35-70. Radiation Survey Instruments.

Survey instruments used in determining compliance with R313-15 and R313-35 shall meet the following requirements:

(1) Instrumentation shall be capable of measuring a range from 0.02 millisieverts (2 millirem) per hour through 0.01 sievert (1 rem) per hour.

(2) Instrumentation shall be calibrated at intervals not to exceed 12 months and after instrument servicing, except for battery changes.

(3) For linear scale instruments, calibration shall be shown at two points located approximately one- third and two-thirds of full-scale on each scale. For logarithmic scale instruments, calibration shall be shown at mid- range of each decade, and at two points of at least one decade. For digital instruments, calibration shall be shown at three points between 0.02 and 10 millisieverts (2 and 1000 millirems) per hour.

(4) An accuracy of plus or minus 20 percent of the calibration source shall be demonstrated for each point checked pursuant to R313-35-70(3).

(5) The registrant shall perform visual and operability checks of survey instruments before use on each day the survey instrument is to be used to ensure that the equipment is in good working condition. If survey instrument problems are found, the equipment shall be removed from service until repaired.

(6) Results of the instrument calibrations showing compliance with R313-35-70(3) and R313-35-70(4) shall be recorded and maintained for a period of three years from the date the record is made.

(7) Records demonstrating compliance with R313-35-70(5) shall be made when a problem is found. The records shall be maintained for a period of three years from the date the record is made.

R313-35-80. Cabinet X-ray Systems.

(1) The requirements as found in 21 CFR 1020.40, 1996 ed., are adopted and incorporated by reference.

(2) Individuals operating cabinet x-ray systems with conveyor belts shall be able to observe the entry port from the operator's position.

R313-35-90. Portable Package Inspection Systems.

Portable package inspection systems shall be registered in accordance with R313-16 and shall be exempt from inspection by representatives of the Executive Secretary.

R313-35-100. Analytical X-Ray Systems Excluding Cabinet X-Ray Systems.

(1) Equipment. Analytical x-ray systems not contained in cabinet x-ray systems shall meet all the following requirements.

(a) A device which prevents the entry of portions of an individual's body into the primary x-ray beam path, or which causes the beam to be shut off upon entry into its path, shall be provided for open-beam configurations.

(i) Pursuant to R313-12-55(1), an application for an exemption from R313-35-100(1)(a) shall contain the following information:

(A) a description of the various safety devices that have been evaluated;

(B) the reason that these devices cannot be used; and

(C) a description of the alternative methods that will be employed to minimize the possibility of

an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(ii) applications for exemptions to R313-35-100(1)(a) shall be submitted to the Executive Secretary of the Board.

(b) Open-beam configurations shall be provided with a readily discernible indication of:

(i) the "on" or "off" status of the x-ray tube which shall be located near the radiation source housing if the primary beam is controlled in this manner; or

(ii) the "open" or "closed" status of the shutters which shall be located near ports on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified and the devices shall be conspicuous at the beam port. On equipment installed after July 1, 1989, warning devices shall have fail-safe characteristics.

(d) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening. Security requirements will be deemed met if the beam port cannot be opened without the use of tools that are not part of the closure.

(e) Analytical x-ray systems shall be labeled with a readily discernable sign or signs bearing a radiation symbol which meets the requirements of R313-15-901 and the words:

(i) "CAUTION-HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray tube housing; and

(ii) "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near switches that energize an x-ray tube.

(f) On analytical x-ray systems with open-beam configurations which are installed after July 1, 1989, ports on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(g) An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near switches that energize an x-ray tube and near x-ray ports. They shall be illuminated only when the tube is energized.

(h) On analytical x-ray systems installed after July 1, 1989, warning lights shall have fail-safe characteristics.

(i) X-ray generators shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface so that they are not capable of producing a dose equivalent in excess of 2.5 microsieverts (0.25 millirem) in one hour.

(j) The components of an analytical x-ray system located in an uncontrolled area shall be arranged and include sufficient shielding or access control so that no radiation levels exist in areas surrounding the component group which could result in a dose to an individual present therein in excess of the dose limits given in R313-15-301.

(2) Personnel Requirements.

(a) An individual shall not be permitted to operate or maintain an analytical x-ray system unless the individual has received instruction which satisfies the requirements of R313-18-12(1). The instruction shall include:

(i) identification of radiation hazards associated with the use of the analytical x-ray system;

(ii) the significance of the various radiation warnings and safety devices incorporated into the analytical x-ray system, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in these cases;

(iii) proper operating procedures for the analytical x-ray system;

(iv) symptoms of an acute localized exposure; and

(v) proper procedures for reporting an actual or suspected exposure.

(b) Registrants shall maintain records which demonstrate compliance with the requirements of R313-35- 100(2)(a) for a period of three years after the termination of the individual.

(c) Normal operating procedures shall be written and available to analytical x-ray system workers. An individual shall not be permitted to operate analytical x-ray systems using procedures other than those specified in the normal operating procedures unless the individual has obtained written approval of the registrant or the registrant's designee.

(d) An individual shall not bypass a safety device unless the individual has obtained the written approval of the registrant or the registrant's designee. Approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(3) Personnel Monitoring. In addition to the requirements of R313-15-502, finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) analytical x-ray system workers using equipment having an open-beam configuration and not equipped with a safety device; and

(b) personnel maintaining analytical x-ray systems if the maintenance procedures require the presence of a primary x-ray beam when local components in the analytical x-ray system are disassembled or removed.

(4) Posting. Areas or rooms containing analytical x-ray systems not considered to be cabinet x-ray systems shall be conspicuously posted to satisfy the requirements in R313-15-902.

R313-35-110. Veterinary X-Ray Systems.

(1) Equipment. X-ray systems shall meet the following standards to be used for veterinary radiographic examinations.

(a) The leakage radiation from the diagnostic source assembly measured at a distance of one meter shall not exceed 25.8 uC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors.

(b) Diaphragms, cones, or a stepless adjustable collimator shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the diagnostic source housing.

(c) A device shall be provided to terminate the exposure after a preset time or exposure.

(d) A "dead-man type" exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator may stand out of the useful beam and at least six feet from the animal during x-ray exposures.

(e) For stationary or mobile x-ray systems, a method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed six percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(f) For portable x-ray systems, a method shall be provided to align the center of the x-ray field with respect to the center of the image receptor to within six percent of the source to image receptor distance, and to indicate the source to image receptor distance to within six percent.

(2) Structural shielding. For stationary x-ray systems, the wall, ceiling, and floor areas shall provide enough shielding to meet the requirements of R313-15-301.

(3) Operating procedures.

(a) Where feasible, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

(b) In applications in which the operator is not located beyond a protective barrier, clothing consisting of a protective apron having a lead equivalent of not less than 0.5 millimeters shall be worn by the operator and other individuals in the room during exposures.

(c) An individual other than the operator shall not be in the x-ray room while exposures are being made unless the individual's assistance is required.

(d) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, for example, protective gloves and apron. The individual shall be so positioned that no unshielded part of that individual's body will be struck by the useful beam.

R313-35-120. X-Ray Systems Less than 1 MeV used for Non-Destructive Testing.

(1) Cabinet x-ray systems.

Cabinet x-ray systems shall meet the requirements of R313-35-80.

(2) Fixed Gauges.

(a) Warning Devices. A light, which is clearly visible from all accessible areas around the x-ray system, shall indicate when the x-ray system is operating.

(b) Personnel Monitoring. Notwithstanding R313-15-502(1)(a), individuals conducting x-ray system maintenance requiring the x-ray beam to be on shall be provided with and required to

wear personnel monitoring devices.

(3) Industrial and Other X-ray Systems.

(a) Equipment.

(i) The registrant shall perform visual and operability checks of indication lights and warning lights before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment shall be removed from service until repaired.

(ii) Inspection and routine maintenance of x-ray systems, interlocks, indication lights, exposure switches, and cables shall be made at intervals not to exceed six months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(iii) Records demonstrating compliance with R313-35-120(3)(a)(i) shall be made when problems with the equipment are found. These records shall be maintained for a period of three years.

(iv) Records demonstrating compliance with R313-35-120(3)(a)(ii) shall be made. These records shall be maintained for a period of three years.

(b) Controls. X-ray systems which produce a high radiation area shall be controlled to meet the requirements of R313-15-601.

(c) Personnel Monitoring Requirements.

(i) Registrants shall not permit individuals to conduct x-ray operations unless all of the following conditions are met.

(A) Individuals shall wear a thermoluminescent dosimeter or film badge.

(I) Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

(II) Film badges shall be replaced at periods not to exceed one month and thermoluminescent dosimeters shall be replaced at periods not to exceed three months.

(B) Individuals shall wear a direct reading dosimeter if conducting non-destructive testing at a temporary job site or in a room or building not meeting the requirements of R313-15-301.

(I) Pocket dosimeters shall have a range from zero to two millisieverts (200 millirem) and must be recharged at the beginning of each shift.

(II) Direct reading dosimeters shall be read and the exposures recorded at the beginning and end of each shift. Records shall be maintained for three years after the record is made.

(III) Direct reading dosimeters shall be checked at intervals not to exceed 12 months for correct response to radiation and the results shall be recorded. Records shall be maintained for a period three years from the date the record is made. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(IV) If an individual's ion-chamber pocket dosimeter is found to be off scale or if the individual's electronic personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's film badge or thermoluminescent dosimeter shall be sent for processing within 24 hours. In addition, the individual shall not resume work with sources of radiation until a determination of the individual's radiation exposure has been made.

(d) Controls. In addition to the requirements of R313-15-601, barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with R313-15-902.

(e) Surveillance. During non-destructive testing applications conducted at a temporary job site or in a room or building not meeting the requirements of R313-15-301, the operator shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area.

R313-35-130. X-Ray Systems Greater than 1 MeV used for Non-Destructive Testing.

(1) Equipment.

(a) Individuals shall not receive, possess, use, transfer, own, or acquire a particle accelerator unless it is registered pursuant to R313-16-231.

(b) The registrant shall perform visual and operability checks of indication lights and warning lights before use on each day the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment shall be removed from service until repaired.

(c) Inspection and routine maintenance of x-ray systems, interlocks, indication lights, exposure switches, and cables shall be made at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment shall be removed from service until repaired.

(d) Records demonstrating compliance with R313-35-130(1)(b) shall be made when problems with the equipment are found. These records shall be maintained for a period of three years.

(e) Records demonstrating compliance with R313-35-130(1)(c) shall be made. These records shall be maintained for a period of three years.

(f) Maintenance performed on x-ray systems shall be in accordance with the manufacturer's specifications.

(g) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(h) A switch on the accelerator control console shall be routinely used to turn the accelerator beam off and on. The safety interlock system shall not be used to turn off the accelerator beam, except in an emergency.

(2) Shielding and Safety Design Requirements.

(a) An individual who has satisfied a criterion listed in R313-16-400, shall be consulted in the design of a particle accelerator's installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Particle accelerator installations shall be provided with primary or secondary barriers which are sufficient to assure compliance with R313-15-201 and R313-15-301.

(c) Entrances into high radiation areas or very high radiation areas shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

(d) When a radiation safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls first at the position where the interlock has been tripped, and then at the main control console.

(e) Safety interlocks shall be on separate electrical circuits which shall allow their operation independently of other safety interlocks.

(f) Safety interlocks shall be fail-safe. This means that they must be designed so that defects or component failures in the interlock system prevent operation of the accelerator.

(g) The registrant may apply to the Executive Secretary for approval of alternate methods for controlling access to high or very high radiation areas. The Executive Secretary may approve the proposed alternatives if the registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high or very high radiation area, and the alternative method does not prevent individuals from leaving a high or very high radiation area.

(h) A "scram" button or other emergency power cutoff switch shall be located and easily identifiable in high radiation areas or in very high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

(i) Safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months, and after maintenance on the safety and warning devices. Results of these tests shall be maintained for inspection at the accelerator facility for three years.

(j) A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

(k) Locations designated as high radiation areas or very high radiation areas and entrances to locations designated as high radiation areas or very high radiation areas shall be equipped with easily observable flashing or rotating warning lights that operate when radiation is being produced.

(l) High radiation areas or very high radiation areas shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of the high radiation area or the very high radiation area. Warning devices shall be clearly discernible in high radiation areas or in very high radiation areas. The registrant shall instruct personnel in the vicinity of the particle accelerator as to the meaning of this audible warning signal.

(m) Barriers, temporary or otherwise, and pathways leading to high radiation areas or very high radiation areas shall be identified in accordance with R313-15-902.

(3) Personnel Requirements.

(a) Registrants shall not permit individuals to act as particle accelerator operators until the individuals have complied with the following:

(i) been instructed in radiation safety; and

(ii) been instructed pursuant to R313-35-50 and the applicable requirements of R313-15.

(iii) Records demonstrating compliance with R313-35-130(3)(a)(i) and R313-35-130(3)(a)(ii) shall be maintained for a period of three years from the termination date of the individual.

(b) Registrants shall not permit an individual to conduct x-ray operations unless the individual meets the personnel monitoring requirements of R313-35-120(3)(c).

(4) Radiation Monitoring Requirements.

(a) At particle accelerator facilities, there shall be available appropriate portable monitoring equipment which is operable and has been calibrated for the radiations being produced at the facility. On each day the particle accelerator is to be used, the portable monitoring equipment shall be tested for proper operation.

(b) When changes have been made in shielding, operation, equipment, or occupancy of adjacent areas, a radiation protection survey shall be performed and documented by an individual who has satisfied a criterion listed in R313-16-400 or the individual designated as being responsible for radiation safety.

(c) Records of radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by representatives of the Board or the Executive Secretary for a period of three years.

R313-35-140. Duties and Authorities of a Radiation Safety Officer.

Facilities operating x-ray systems under R313-35-130 shall appoint a Radiation Safety Officer. The specific duties and authorities of the Radiation Safety Officer include, but are not limited to:

(1) establishing and overseeing all operating, emergency, and ALARA procedures as required by R313- 15;

(2) ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the registrant's program;

(3) overseeing and approving the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

(4) ensuring that required radiation surveys are performed and documented in accordance with the R313-35-130(4);

(5) ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by R313-15-1203; and

(6) ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

KEY

industry, x-ray, veterinarians, surveys

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Rule R313-36. Special Requirements for Industrial Radiographic Operations.

As in effect on September 1, 2002

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R313-36-1. Purpose and Authority.

(1) The rules in R313-36 prescribe requirements for the issuance of licenses and establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3) and 19-3-104(6).

(3) The requirements of R313-36 are in addition to, and not in substitution for, the other requirements of these rules.

R313-36-2. Scope.

(1) The requirements of R313-36 shall apply to licensees using radioactive materials to perform industrial radiography.

(2) The requirements of R313-36 shall not apply to persons using electronic sources of radiation to conduct industrial radiography.

R313-36-3. Clarifications or Exceptions.

For purposes of R313-36, 10 CFR 34 (2001), is incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: "34.1", "34.5", "34.8", "34.11", "34.121", and "34.123";

(2) The exclusion of "10 CFR 34.45(a)(9)";

(3) The exclusion of the following 10 CFR references within 10 CFR 34: "21", "30.7", "30.9", and "30.10";

(4) The exclusion of "offshore" in 10 CFR 34.3 definition for "offshore platform radiography";

(5) The substitution of the following wording:

(a) "Utah Radiation Control Rules" for the reference to:

(i) "Commission's regulations", except as stated in R313-36-3(5)(f);

(ii) "Federal regulations"; and

(iii) "NRC regulations";

(b) "Executive Secretary" for the reference to "Commission", except as stated in 10 CFR 34.20 and R313-36-3(5)(c)(iv);

(c) "Executive Secretary, U.S. Nuclear Regulatory Commission, or an Agreement State" for references to:

(i) "NRC or an Agreement State";

(ii) "Commission or by an Agreement State";

(iii) "Commission or an Agreement State"; and

(iv) "Commission" in 10 CFR 34.43(a)(2);

(d) "License" for reference to "NRC license(s)";

(e) In 10 CFR 34.27(d), "reports of test results for leaking or contaminated sealed sources shall be made pursuant to R313-15-1208.", for reference to the following statements:

(i) "A report must be filed with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days of any test with results that exceed the threshold in this subsection, describing the equipment involved, the test results, and the corrective action taken."; and

(ii) "A copy of the report must be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter "Standards for Protection Against Radiation.";

(f) In 10 CFR 34.27(d), "R313-15-401(6)" for the reference to "Commission regulations";

(g) In 10 CFR 34.89, "a U.S. Nuclear Regulatory Commission or an Agreement State" for the reference to "the Agreement State";

(h) In 10 CFR 34.101(a), "Executive Secretary" for the following wording:

(i) "U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, Washington, D.C. 20555-0001, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001";

(i) In 10 CFR 34.101(c), "Executive Secretary" for the reference to "appropriate NRC regional office listed in 10 CFR 30.6(a)(2) of this chapter";

(j) In Item 12, Section I of Appendix A to 10 CFR 34, "Executive Secretary, the U.S. Nuclear Regulatory Commission and other independent certifying organizations and/or Agreements States" for the reference to "Commission and other independent certifying organizations and/or Agreement States";

(k) In Item 1, Section II of Appendix A to 10 CFR 34, "equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations" for the reference to "equivalent Agreement State regulations"; and

(l) In Item 2(c), Section II of Appendix A to 10 CFR, "a Utah, U.S. Nuclear Regulatory Commission, or an Agreement State licensee" for the reference to "an Agreement State or a NRC licensee"; and

(6) The substitution of the following R313 references for specific 10 CFR references:

(a) "R313-12-55(1)" for reference to "10 CFR 34.111";

(b) "R313-15" for the reference to "10 CFR 20";

(c) "R313-15-601(1)(a)" for the reference to "10 CFR 20.1601(a)(1)";

(d) "R313-15-902" for the reference to "10 CFR 20.1902";

(e) "R313-15-903" for the reference to "10 CFR 20.1903";

(f) "R313-15-1203" for the reference to "10 CFR 20.2203";

(g) "R313-18" for the reference to "10 CFR 19";

(h) "R313-19-30" for the reference to "10 CFR 150.20";

(i) "R313-19-50" for the reference to "10 CFR 30.50";

(j) "R313-19-100" for the reference to "10 CFR 71", "10 CFR 71.5", and "49 CFR 171 to 173";

(k) "R313-22-33" for the reference to "10 CFR 30.33"; and

(l) "R313-36" for the reference to "10 CFR 34."

KEY

industry, radioactive material, licensing, surveys

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19-3-104; 19-3-108

Rule converted into HTML by the Division of Administrative Rules.

For questions regarding the *content* or *application* of rules under Title R313, please contact the promulgating agency (Environmental Quality, Radiation Control). A list of agencies with links to their homepages is available at **http://www.utah.gov/government/agencylist.html.**

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Rule R313-38. Licenses and Radiation Safety Requirements for Well Logging.

As in effect on September 1, 2002

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R313-38-1. Purpose and Authority.

(1) Rule R313-38 prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This rule also prescribes radiation safety requirements for persons using licensed materials in these operations.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(3) and 19-3-104(6).

(3) The provisions and requirements of Rule R313-38 are in addition to, and not in substitution for, the other requirements of these rules. In particular, the provisions of Rules R313-15, R313-18, R313-19, and R313-22 apply to applicants and licensees subject to these rules.

R313-38-2. Scope.

(1) The requirements of Rule R313-38 do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

R313-38-3. Clarifications or Exceptions.

For purposes of Rule R313-38, 10 CFR 39 (2001), is incorporated by reference with the following

clarifications or exceptions:

(1) The exclusion of the following 10 CFR sections: 39.1, 39.5, 39.8, 39.11, 39.101, and 39.103;

(2) The exclusion of the following 10 CFR references within 10 CFR 39: Sec. 40.32, and Sec. 70.33;

(3) The exclusion of "licensed material" in 10 CFR 39.2 definitions;

(4) The substitution of the following wording:

(a) License for reference to NRC license;

(b) Utah Radiation Control Rules for the references to:

(i) The Commission's regulations;

(ii) The NRC regulations;

(iii) NRC regulations; and

(iv) Pertinent Federal regulations;

(c) Executive Secretary for reference to Commission, except as stated in Subsection R313-38- 3 (4)(d);

(d) Representatives of the Executive Secretary for the references to the Commission in:

(i) 10 CFR 39.33(d);

(ii) 10 CFR 39.35(a);

(iii) 10 CFR 39.37;

(iv) 10 CFR 39.39(b); and

(v) 10 CFR 39.67(f);

(e) Executive Secretary or the Executive Secretary for references to:

(i) NRC in:

(A) 10 CFR 39.63(l);

(B) 10 CFR 39.77(c)(1)(i) and (ii); and

(C) 10 CFR 39.77(d)(9); and

(ii) Appropriate NRC Regional Office in:

(A) 10 CFR 39.77(a);

(B) 10 CFR 39.77(c)(1); and

(C) 10 CFR 39.77(d);

(f) Executive Secretary, the U.S. Nuclear Regulatory Commission or an Agreement State for the references to:

(i) Commission or an Agreement State in:

(A) 10 CFR 39.35(b); and

(B) 10 CFR 39.43(d) and (e); and

(ii) Commission pursuant to Sec. 39.13(c) or by an Agreement State in:

(A) 10 CFR 39.43(c); and

(B) 10 CFR 39.51;

(g) In 10 CFR 39.35(d)(1), persons specifically licensed by the Executive Secretary, the U.S. Nuclear Regulatory Commission, or an Agreement State for the reference to an NRC or Agreement State licensee that is authorized; and

(h) In 10 CFR 39.35(d)(2), reports of test results for leaking or contaminated sealed sources shall be made pursuant to Section R313-15-1208, for the reference to the following statement:

(i) The licensee shall submit a report to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter, within 5 days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made; and

(i) In 10 CFR 39.75(e), a U.S. Nuclear Regulatory Commission or an Agreement State for the reference to the Agreement State;

(5) The substitution of the following Title R313 references for specific 10 CFR references:

(a) Section R313-12-3 for the reference to Sec. 20.1003 of this chapter;

(b) Section R313-12-54 for the reference to 10 CFR 39.17;

(c) Subsection R313-12-55(1) for the reference to 10 CFR 39.91;

(d) Rule R313-15 for references to:

(i) Part 20; and

(ii) Part 20 of this chapter;

(e) Subsection R313-15-901(1) for the reference to Sec. 20.1901(a);

(f) Section R313-15-906 for the reference to Sec. 20.205 of this chapter;

(g) Sections R313-15-1201 through R313-15-1203 for the references to:

(i) Secs. 20.2201-20.2202; and

(ii) Sec. 20.2203;

(h) Rule R313-18 for the reference to part 19;

(i) Section R313-19-30 for the reference to Sec. 150.20 of this chapter;

(j) Section R313-19-50 for the references to:

(i) Sec. 30.50; and

(ii) Part 21 of this chapter;

(k) Section R313-19-71 for the reference to Sec. 30.71;

(l) Section R313-19-100 for the references to:

(i) 10 CFR Part 71; and

(ii) Sec. 71.5 of this chapter; and

(m) Section R313-22-33 for the reference to 10 CFR 30.33;

KEY

radioactive material, well logging, surveys, subsurface tracer studies

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Rules. *Please Note:* The Division of Administrative Rules is ***not able*** to answer questions about the content or application of these rules.

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Rule R313-70. Payments, Categories and Types of Fees.

As in effect on September 1, 2002

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R313-70-1. General.

R313-70 applies to persons who receive, possess, or use sources of radiation provided, however, that nothing in these rules shall apply to the extent a person is subject to regulations by the U.S. Nuclear Regulatory Commission. The fees charged are authorized by subsection 19-3-104(4) of the Environmental Quality Code.

R313-70-3. Communications.

Communications concerning the rules in R313-70 should be addressed to the Executive Secretary, and may be sent to the Division of Radiation Control, Department of Environmental Quality. Communications may be delivered in person at the Division of Radiation Control offices.

R313-70-5. Payment of Fees.

(1) New Application Fee: Applications for machine registration or radioactive material licensing for which a fee is prescribed, shall be accompanied by a remittance in the full amount of the fee. Applications will not be accepted for filing or processing prior to payment of the full amount specified. Applications for which no remittance is received will be returned to the applicant. Application fees will be charged irrespective of the Executive Secretary's disposition of the application or a withdrawal of the application.

(2) Annual Fee: Persons and individuals who are subject to licensing or registration of radioactive material or radiation machine registration with the Department of Environmental Quality under provisions of the Utah Radiation Control Rules, are assessed an annual fee in accordance with categories of R313-70-7 and R313-70-8. The appropriate fee shall be filed annually with the Executive Secretary, by July 30 for registrants or by the anniversary date for licensees. Fees for radiation machine registration will be considered late if not received annually by the last day of August. Licensees may be assessed late fees if license fees are not received within 30 days after the license anniversary date. Late fees may also be assessed for successive 30 day periods during which the annual fee or registration fee remains unpaid.

(3) Inspection Fee: Persons and entities who, under provisions of the Utah Radiation Control Rules, are subject to radiation machine registration with the Department of Environmental Quality are assessed an inspection fee in accordance with R313-70-8. Fees for inspection of a radiation machine are due within 30 days of receipt of an invoice from the Agency. Registrants may be assessed late fees if inspection fees are not received in a timely manner.

(4) Failure to pay the prescribed fee: the Executive Secretary will not process applications and may suspend or revoke licenses or registrations or may issue an order with respect to the activities as the Executive Secretary determines to be appropriate or necessary in order to carry out the provisions of this part of R313-70, and of the Act.

(a) General license certificates of registration and specific licenses issued pursuant to the provisions in R313-21 or R313-22, will be valid for a period of five years unless failure to submit appropriate fee occurs. Machine registrations will be valid for one year during the interval outlined in R313-16-230. Failure to submit appropriate fees will render the license, certificate or registration invalid, at which time a new application with appropriate fees shall be submitted.

(b) Renewal applications shall be filed in a timely manner in accordance with R313-22-37 or R313-16- 230. The radioactive material license will expire on the date specified on the license. Machine registration will expire as outlined in R313-16-230. An expired license cannot be renewed, rather the licensee will be required to submit an application for a new license and submit the appropriate application and new license fee.

(4) Method of Payment: Fees shall be made payable to: Division of Radiation Control, Department of Environmental Quality.

R313-70-7. License Categories and Types of Fees for Radioactive Materials Licenses.

Fees shall be established in accordance with the Legislative Appropriations Act. Copies of established fee schedules may be obtained from the Executive Secretary.

TABLE

LICENSE CATEGORY	TYPE OF FEE
(1) Special Nuclear Material	
(a) Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems,	New License or Renewal Annual Fee

including x-ray fluorescence analyzers and neutron generators.	
(b) Licenses for possession and use of less than 15 g special nuclear material in unsealed form for research and development.	New License or Renewal Annual Fee
(c) All other special nuclear material licenses.	New License or Renewal Annual Fee
(d) Special nuclear material to be used as calibration and reference sources.	New License or Renewal Annual Fee
(2) Source Material.	
(a) Licenses for concentrations of uranium from other areas like copper or phosphates for the production of moist, solid, uranium yellow cake.	New License or Renewal Annual Fee
(b) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, ore buying stations, and ion exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	Annual Fee
(c) Licenses that authorize the receipt of byproduct material, as [illegible] 19-3-102, from other persons for possession and disposal.	Annual Fee

(d) Licenses that authorize the receipt of byproduct material, as defined in Section 19-3-102, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations.	Annual Fee
(e) Licenses for possession and use of source material for shielding.	New License or Renewal Annual Fee
(f) All other source material licenses.	New License or Renewal Annual Fee
(3) Radioactive Material Other than Source Material and Special Nuclear Material.	
(a)(i) Licenses of broad scope for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.	New License or Renewal Annual Fee
(a)(ii) Other licenses for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.	New License or Renewal Annual Fee
(b) Licenses authorizing the processing or manufacturing and distribution or redistribution of radio-pharmaceuticals, generators, reagent kits, or sources or devices containing radioactive material.	New License or Renewal Annual Fee
(c) Licenses authorizing distribution or	New License or Renewal Annual Fee

redistribution of radiopharmaceuticals, generators, reagent kits, or sources or devices not involving processing of radioactive material.	
(d) Licenses for possession and use of radioactive material for industrial radiography operations.	New License or Renewal Annual Fee
(e) Licenses for possession and use of sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).	New License or Renewal Annual Fee
(f)(i) Licenses for possession and use of less than 10,000 curies of radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	New License or Renewal Annual Fee
(f)(ii) Licenses for possession and use of 10,000 curies or more of radioactive material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes.	New License or Renewal Annual Fee
(g) Licenses to distribute items containing radioactive material that require device review to persons exempt from the	New License or Renewal Annual Fee

licensing requirements of R313-19, except specific licenses authorizing redistribution of items that have have been authorized for distribution to persons exempt from the licensing requirements of R313-19.	
(h) Licenses to distribute items containing radioactive material or quantities of radioactive material that do not require device evaluation to persons exempt from the licensing requirements of R313-19, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of R313-19.	New License or Renewal Annual Fee
(i) Licenses to distribute items containing radio-active material that require sealed source or device review to persons generally licensed under R313-21, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under R313-21.	New License or Renewal Annual Fee
(j) Licenses to distribute items containing radioactive material or quantities of	New License or Renewal Annual Fee

radioactive material that do not require sealed source or device review to persons generally licensed under R313-21, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under R313-21.	
(k) Licenses for possession and use of radioactive material for research and development, which do not authorize commercial distribution.	New License or Renewal Annual Fee
(l) All other specific radioactive material licenses.	New License or Renewal Annual Fee
(m) Licenses of broad scope for possession and use of radioactive material for research and development which do not authorize commercial distribution.	New License or Renewal
(n) Licenses that authorize services for other licensees, except licenses that authorize leak testing or waste disposal services which are subject to the fees specified for the listed services.	New License or Renewal Annual Fee
(o) Licenses that authorize services for leak testing only.	New License or Renewal Annual Fee
(4) Radioactive Waste Disposal:	
(a) Licenses specifically authorizing the receipt of	Application Fee New License or Renewal

waste radioactive material from other persons for the purpose of commercial disposal by land by the licensee.	
(b) Licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	New License or Renewal Annual Fee
(c) Licenses specifically authorizing the receipt of prepackaged waste radioactive material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.	New License or Renewal Annual Fee
(d) Licenses authorizing packaging of radioactive waste for shipment to waste disposal site where licensee does not take possession of waste material.	New License or Renewal Annual Fee
(5) Well logging, well surveys and tracer studies.	
(a) Licenses for possession and use of radioactive material	New License or Renewal Annual Fee

for well logging, well surveys and tracer studies other than field flooding tracer studies.	
(b) Licenses for possession and use of radioactive material for field flooding tracer studies.	New License or Renewal Annual Fee
(6) Nuclear laundries.	
(a) Licenses for commercial collection and laundry of items contaminated with radioactive material.	New License or Renewal Annual Fee
(7) Human use of radioactive material.	
(a) Licenses for human use of radioactive material in sealed sources contained in teletherapy devices.	New License or Renewal Annual Fee
(b) Other licenses issued for human use of radioactive material, except licenses for use of radioactive material contained in teletherapy devices.	New License or Renewal Annual Fee
(c) Licenses of broad scope issued to medical institutions or two or more physicians authorizing research and development, including human use of radioactive material, except licenses for radio-active material in sealed sources contained in teletherapy devices.	New License or Renewal Annual Fee
(8) Civil Defense.	
(a) Licenses for possession and use of radioactive material for civil	New License or Renewal Annual Fee

defense activities.	
(9) Power Source.	
(a) Licenses for the manufacture and distribution of encapsulated radioactive material wherein the decay energy of the material is used as a source for power.	New License or Renewal Annual Fee
(10) General License.	
(a) Measuring, gauging and control devices as described in R313-21-22(4), other than hydrogen-3 (tritium) devices and polonium-210 devices containing no more than 10 millicuries used for producing light or an ionized atmosphere.	Fee per registration certificate
(b) In Vitro testing	Fee per registration certificate
(c) Depleted uranium	Fee per registration certificate
(d) Reciprocal recognition, as provided for in R313-19-30, of a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.	Annual fee for license category listed in R313-70-7(1) through (10), per 180 days in one calendar year

R313-70-8. Registration and Inspection Categories and Types of Fees for Registration of Radiation Machines.

(1) For machines registered under R313-16-230, registrants will pay an annual registration fee and an inspection fee that shall be established in accordance with the Legislative Appropriations Act. Copies of established fee schedules may be obtained from the Executive Secretary.

TABLE

FACILITY TYPE	TYPE OF FEE	
Hospital/Therapy	Registration	Annual per control unit and first tube plus annual per each additional tube

		connected to a control unit.
	State Inspection	Per tube.
Medical	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Podiatry	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Veterinary	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Chiropractic	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Dental	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per control unit and first tube plus each additional tube connected to a control unit.
Industrial Facility with High or Very High Radiation Areas Accessible to Individuals	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Industrial Facility with Cabinet X-ray or Units Designed	Registration	Annual per control unit and first tube plus annual

for Other Industrial Purposes		per each additional tube connected to a control unit.
	State Inspection	Per tube.
Other	Registration	Annual per control unit and first tube plus annual per each additional tube connected to a control unit.
	State Inspection	Per tube.
Acceptance of work, performed by a person meeting the qualifications in R313-16-400, that demonstrates compliance with these rules.		Per tube reviewed.

R313-70-9. Other Fees for Services.

TABLE

(1) Expedited application review. Applicable when, by mutual consent of the applicant and affected staff, an application request is taken out of date order and processed by staff during non-work hours.	Hourly
(2) Review of plans for decommissioning, decontamination, reclamation, or site restoration activities.	Plan Review Plus Hourly
(3) Management and oversight of impounded radioactive material.	Actual Cost
(4) License amendment, for greater than three applications in a calendar year.	Amendment Fee

KEY

radioactive material, x-rays, registration, fees

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